

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

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Footnotes:

Note: Asterisk indicates an imputed date. A Treatment-Emergent Adverse Event (TEAE) is defined as any adverse event with an onset date on or after the date of first dose, or any ongoing adverse event that worsens in severity or relationship on or after the date of first dose up to and including 30 days after the date of last dose.

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth +1)/365.25.

[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX= ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.

[3] From the MedDRA 18.0 dictionary.

[4] Frequency: C=Continuous, I=Intermittent

[5] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Recovered/Resolved with Sequelae, 4 = Not Recovered/Not Resolved, 5 = Fatal, 99 = Unknown.

[6] Any Treatment Required: 1 = None, 2 = Concomitant Medications, 3 = Non-Drug Therapies, 4 = Concomitant Medications and Non-Drug Therapies.

[7] Action Taken to Study Drug: 1 = No Action Taken, 2 = Permanently Discontinued, 3 = Stopped Temporarily. If stopped, stop and restart dates are provided. Even though the Action Taken was checked as 'Stopped Temporarily', some patients did not resume treatment. For these patients, the restart date is marked as 'Unknown'.

[8] Relation to Study Drug: 1 = Definitely Related, 2 = Probably Related, 3 = Possibly Related, 4 = Unlikely Related, 5 = Not Related. If Relationship to study drug is 'Not Related' or 'Unlikely', Unrelated Relationship to Study Drug is provided as: PD=Disease Progression, CM=Concomitant Medication, CD=Concomitant Disease, OTH=Other.

[9] CTCAE Grade: 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life-threatening, 5 = Fatal.

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Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
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Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0001/59 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Epistaxis/ EPITAXIS	02NOV2011 /99	03NOV2011 /-57	C	1	0	1	5	1
	General disorders and administration site conditions/ Swelling/ CHEST THORACIC SWELLING OF STERNAL REGION	21OCT2011 /87	10NOV2011 /-50	I	1	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	24AUG2011 /29	05SEP2011 /-116	C	1	0	1	3	1
	Reproductive system and breast disorders/ Genital rash/ RASH - TESTICULAR	02AUG2011 /7	09AUG2011 /-143	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

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101-0001/59 /M/A2/Y	General disorders and administration site conditions/ Fatigue/ FATIGUE	27JUL2011 /1	09AUG2011 /-143	I	1	0	1	3	1
	Nervous system disorders/ Peripheral sensory neuropathy/ SENSORY NEUROPATHY - FINGERS, TOES	07SEP2011 /43	Unknown/NA	I	6	0	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ UPPER AND LOWER EXTREMITY PRURITIS	09AUG2011 /14	15AUG2011 /-137	C	1	1	3 /09AUG2011 /16AUG2011	2	2
	General disorders and administration site conditions/ Injection site rash/ RASH - UPPER AND LOWER EXTREMITIES RASH AT INJECTION SITE	17AUG2011 /22	05SEP2011 /-116	C	1	1	1	1	1

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Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

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101-0005/77 /M/W2/N	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	13SEP2011 /35	19SEP2011 /-29	C	1	1	1	3	1
101-0006/62 /M/W2/N	Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	07OCT2011 /56	13OCT2011 /6	I	1	0	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	09SEP2011 /28	13OCT2011 /6	I	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	13AUG2011 /1	07OCT2011 /0	C	1	1	1	5	1

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Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

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101-0006/62 /M/W2/N	Renal and urinary disorders/ Nocturia/ NOCTURIA	02SEP2011 /21	08SEP2011 /-29	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Epistaxis/ EPITAXIS	24AUG2011 /12	02SEP2011 /-35	I	1	0	1	4	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	02SEP2011 /21	Unknown/NA	C	6	0	1	2	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	09SEP2011 /28	07OCT2011 /0	I	1	0	1	5	1

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Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

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101-0007/77 /M/A1/Y	Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	14SEP2011 /22	27SEP2011 /-35	I	1	0	1	5	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	26SEP2011 /34	04OCT2011 /-28	C	1	0	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LOWER EXTREMITY EDEMA	23AUG2011 /0	30AUG2011 /-63	C	1	0	1	5	2
	Renal and urinary disorders/ Dysuria/ DIFFICULTY URINATING	02DEC2011 /101	29DEC2011 /58	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

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101-0007/77 /M/A1/Y	Infections and infestations/ Tooth abscess/ TOOTH ABSCESS	16NOV2011 /85	09DEC2011 /38	C	1	0	1	5	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	23AUG2011 /0	30AUG2011 /-63	C	1	0	1	4	1
	Musculoskeletal and connective tissue disorders/ Back pain/ LOWER BACK PAIN	23AUG2011 /0	06SEP2011 /-56	C	1	0	1	5	1
101-0008/83 /M/BL/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	19OCT2011 /54	31OCT2011 /-8	I	1	0	1	3	1

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Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

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101-0008/83 /M/BL/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	02SEP2011 /7	08SEP2011 /-61	C	1	0	1	5	1
	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINEMIA	19SEP2011 /24	03OCT2011 /-36	I	1	0	3 /20SEP2011 /04OCT2011	3	3
	General disorders and administration site conditions/ Fatigue/ FATIGUE	09SEP2011 /14	19SEP2011 /-50	C	1	0	1	3	1
101-0009/82 /M/A1/N	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	08NOV2011 /35	14NOV2011 /-29	C	1	1	3 /08NOV2011 /15NOV2011	2	3

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Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



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101-0009/82 /M/A1/N	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS (BACK)	30DEC2011 /87	Unknown/NA	C	6	1	1	3	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ LEFT SHOULDER PAIN	11OCT2011 /7	13DEC2011 /0	C	1	1	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	04OCT2011 /0	31OCT2011 /-43	C	1	0	1	3	1
	Cardiac disorders/ Supraventricular extrasystoles/ ATRIAL PREMATURE CONTRACTIONS	29NOV2011 /56	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

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101-0009/82 /M/A1/N	Psychiatric disorders/ Anxiety/ ANXIETY	04OCT2011 /0	04OCT2011 /-70	C	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ SHOULDER PAIN	02DEC2011 /59	13DEC2011 /0	C	1	1	1	5	2
101-0011/75 /F/W2/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	23NOV2011 /8	Unknown/NA	C	5	0	1	3	1
	General disorders and administration site conditions/ Disease progression/ DISEASE PROGRESSION NOS	16DEC2011 /31	16DEC2011 /24	C	4	0	1	5[PD]	5

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Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

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101-0011/75 /F/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	23NOV2011 /8	Unknown/NA	C	5	0	1	3	2
	Infections and infestations/ Onychomycosis/ ONYCHOMYCOSIS	22NOV2011 /7	29NOV2011 /7	C	1	1	1	4	1
101-0012/68 /M/W2/N	Skin and subcutaneous tissue disorders/ Rash/ RASH - UPPER LEFT ARM	04JAN2012 /36	09JAN2012 /-1	C	1	1	1	2	2
	Investigations/ Alanine aminotransferase increased/ ELEVATED ALT	06DEC2011 /7	12DEC2011 /-29	C	1	0	3 /06DEC2011 /13DEC2011	3	3

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Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

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101-0012/68 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ LEFT HAND EDEMA	22DEC2011 /23	27DEC2011 /-14	C	1	0	1	5	1
	General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH	11JAN2012 /43	16JAN2012 /6	C	1	1	3 /17JAN2012 /Unknown	2	2
101-0013/66 /F/A5/Y	Investigations/ Blood pressure increased/ WORSENING ELEVATED BLOOD PRESSURE	29JAN2012 /19	07FEB2012 /-91	C	1	1	3 /31JAN2012 /07FEB2012	3	3
	Nervous system disorders/ Paraesthesia/ PARESTHESIAS	28FEB2012 /49	06MAR2012 /-63	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

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101-0013/66 /F/A5/Y	Psychiatric disorders/ Depression/ DEPRESSION	23JAN2012 /13	31JAN2012 /-98	C	1	0	1	5	1
	Psychiatric disorders/ Anxiety/ ANXIETY	29JAN2012 /19	07FEB2012 /-91	C	1	1	1	3	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	05MAY2012 /116	06MAY2012 /-2	C	1	1	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	31JAN2012 /21	07FEB2012 /-91	C	1	0	1	3	1

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Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

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101-0013/66 /F/A5/Y	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	31JAN2012 /21	07FEB2012 /-91	C	1	0	1	3	1
	Hepatobiliary disorders/ Cholangitis/ CHOLANGITIS	14MAY2012 /125	22MAY2012 /14	C	1	1	3 /08MAY2012 /Unknown	5[PD]	3
101-0016/61 /M/A4/Y	General disorders and administration site conditions/ Peripheral swelling/ LEG SWELLING	25JAN2013 /378	25JAN2013 /-35	C	1	1	1	5	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	21FEB2012 /39	28FEB2012 /-367	C	1	0	3 /21FEB2012 /28FEB2012	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

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101-0016/61 /M/A4/Y	Infections and infestations/ Tooth infection/ TOOTH INFECTION	01OCT2012* /262	31OCT2012* /-121	C	1	2	1	5	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	10JUL2012 /179	17JUL2012 /-227	C	1	1	3 /10JUL2012 /17JUL2012	2	3
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT LEG PAIN	19JAN2013 /372	08FEB2013 /-21	I	1	1	1	5	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	20MAR2012 /67	06APR2012 /-329	C	1	1	1	2	3

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Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

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101-0018/51 /M/A1/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	29FEB2012 /8	Unknown/NA	I	6	1	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ WORSENING DYSPNEA	28MAR2012 /36	31MAR2012 /25	C	4	1	1	5 [PD]	5
	General disorders and administration site conditions/ Fatigue/ FATIGUE	22FEB2012 /1	Unknown/NA	C	6	0	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	29FEB2012 /8	11MAR2012 /5	I	3	0	1	3	1

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Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



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101-0018/51 /M/A1/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	12MAR2012 /20	21MAR2012 /15	C	3	1	3 /13MAR2012 /Unknown	5 [PD]	3
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	12MAR2012 /20	Unknown/NA	C	6	0	3 /13MAR2012 /Unknown	5 [PD]	3
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA-ANKLE	29FEB2012 /8	Unknown/NA	C	6	1	1	3	1
101-0019/68 /M/W2/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	07MAY2012 /69	14MAY2012 /6	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

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101-0019/68 /M/W2/N	Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION-WORSENER	06MAR2012 /7	06MAR2012 /-63	C	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Spinal pain/ LUMBAR SPINE TENDERNESS	05JUL2012 /128	30JUL2012 /83	C	1	1	1	5	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	03APR2012 /35	06APR2012 /-32	I	1	1	3 /03APR2012 /10APR2012	4	3
	Endocrine disorders/ Inappropriate antidiuretic hormone secretion/ SIADH	03APR2012 /35	Unknown/NA	C	6	0	3 /03APR2012 /06APR2012	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

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101-0019/68 /M/W2/N	Musculoskeletal and connective tissue disorders/ Bone pain/ BONE PAIN	17APR2012 /49	Unknown/NA	I	6	2	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL ANKLE EDEMA	05JUL2012 /128	30JUL2012 /83	C	1	0	1	5	2
101-0021/74 /M/W2/N	Blood and lymphatic system disorders/ Leukocytosis/ LEUKOCYTOSIS	05JUN2012 /77	19JUN2012 /21	C	1	0	1	5	3
	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINEMIA	10APR2012 /21	05JUN2012 /7	I	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

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101-0022/55 /M/BL/N	General disorders and administration site conditions/ Oedema peripheral/ LEG EDEMA	17APR2012 /28	Unknown/NA	C	6	1	1	5	1
	General disorders and administration site conditions/ Fatigue/ INCREASING FATIGUE	17APR2012 /28	Unknown/NA	C	6	0	1	5	2
	Gastrointestinal disorders/ Ascites/ ASCITES	17APR2012 /28	Unknown/NA	C	6	1	1	5	1
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ PROGRESSION OF DISEASE - HEPATOCELLULAR CARCINOMA	13APR2012 /24	31MAY2012 /58	C	4	0	1	5 [PD]	5

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

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Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0022/55 /M/BL/N	Nervous system disorders/ Encephalopathy/ WORSENING ENCEPHALOPATHY	24APR2012 /35	28APR2012 /25	C	3	1	1	5 [PD]	3
101-0023/70 /M/W2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	20APR2012 /21	21APR2012 /-48	I	1	0	1	4	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	31MAR2012 /1	12APR2012 /-57	C	1	1	1	3	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	24MAY2012 /55	25MAY2012 /-14	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0023/70 /M/W2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	14JUN2012 /76	15JUN2012 /7	C	1	0	1	4	1
	Renal and urinary disorders/ Urinary retention/ URINARY RETENTION	14JUN2012 /76	15JUN2012 /7	C	1	2	1	5	2
	Nervous system disorders/ VIIth nerve paralysis/ INCREASED LEFT-SIDED FACIAL DROOPING	07SEP2012 /161	Unknown/NA	C	6	0	1	5	2
101-0024/35 /F/A4/N	Nervous system disorders/ Dizziness/ DIZZINESS	08MAY2012 /7	15MAY2012 /-56	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0024/35 /F/A4/N	Gastrointestinal disorders/ Vomiting/ VOMITING	29MAY2012 /28	05JUN2012 /-35	I	1	0	1	3	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	08MAY2012 /7	07AUG2012 /28	I	1	0	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	08MAY2012 /7	03JUL2012 /-7	C	1	1	1	3	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	08MAY2012 /7	15MAY2012 /-56	C	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0024/35 /F/A4/N	Skin and subcutaneous tissue disorders/ Rash/ RASH	07AUG2012 /98	13NOV2012 /126	C	1	0	1	2	1
101-0025/57 /F/W2/N	Skin and subcutaneous tissue disorders/ Erythema/ RIGHT DELTOID ERYTHEMA	25MAY2012 /35	08JUN2012 /-7	C	1	1	1	2	2
	Gastrointestinal disorders/ Abdominal pain/ SEVERE WORSENING ABDOMINAL PAIN	28MAY2012 /38	28MAY2012 /-18	C	1	1	1	5	3
	Skin and subcutaneous tissue disorders/ Erythema/ LEFT DELTOID ERYTHEMA	25MAY2012 /35	08JUN2012 /-7	C	1	1	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0025/57 /F/W2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	04MAY2012 /14	11MAY2014 /695	I	1	0	1	4	1
101-0026/82 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	11SEP2012 /119	14SEP2012 /-119	C	1	1	1	4	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	20JUL2012 /66	02AUG2012 /-162	I	1	0	1	3	1
	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LOWER EXTREMITY EDEMA	07SEP2012 /115	10SEP2012 /-123	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0026/82 /M/W2/N	Eye disorders/ Dry eye/ DRY EYES	21SEP2012 /129	21SEP2012 /-112	I	1	0	1	4	1
	Vascular disorders/ Hypertension/ HYPERTENSION	06NOV2012 /175	12NOV2012 /-60	I	1	1	1	5	1
	Hepatobiliary disorders/ Hepatic failure/ HEPATIC FAILURE	28JUN2012 /44	Unknown/NA	I	6	1	3 /29JUN2012 /05JUL2012	4[PD]	3
	Infections and infestations/ Lower respiratory tract infection/ LOWER RESPIRATORY INFECTION	12SEP2012 /120	14SEP2012 /-119	C	1	1	1	4[CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0026/82 /M/W2/N	Nervous system disorders/ Encephalopathy/ ENCEPHALOPATHY	27JUL2012 /73	03AUG2012 /-161	I	1	1	3 /27JUL2012 /03AUG2012	4 [PD]	3
	Infections and infestations/ Pneumonia/ PNEUMONIA	05OCT2012 /143	12OCT2012 /-91	I	1	1	1	5	3
	General disorders and administration site conditions/ Oedema peripheral/ LOWER EXTREMITY EDEMA	13NOV2012 /182	04DEC2012 /-38	I	1	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	12SEP2012 /120	13SEP2012 /-120	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0026/82 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ RIGHT LOWER EXTREMITY EDEMA	21SEP2012 /129	28SEP2012 /-105	C	1	1	1	5	1
	Nervous system disorders/ Encephalopathy/ ENCEPHALOPATHY	17MAY2012 /2	29MAY2012 /-227	C	1	1	3 /22MAY2012 /29MAY2012	5 [PD]	2
101-0028/60 /M/W2/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	10AUG2012 /56	07SEP2012 /17	C	1	1	3 /07AUG2012 /21AUG2012	5 [PD]	3
	Respiratory, thoracic and mediastinal disorders/ Hypoxia/ ACUTE HYPOXIA	12AUG2012 /58	12AUG2012 /-9	C	1	3	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0028/60 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	07AUG2012 /53	17SEP2012 /27	C	1	0	1	3	2
	Investigations/ Blood creatinine increased/ CREATININE INCREASED	19JUN2012 /4	05SEP2012 /15	C	1	1	1	5	2
101-0029/70 /M/A1/Y	General disorders and administration site conditions/ Fatigue/ FATIGUE	26JUN2012 /7	17JUL2012 /-42	I	1	0	1	2	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	14AUG2012 /56	21AUG2012 /-7	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0030/51 /M/W2/N	Renal and urinary disorders/ Costovertebral angle tenderness/ RIGHT COSTOVERTEBRAL ANGLE TENDERNESS	07AUG2012 /33	14AUG2012 /-14	I	1	0	1	5	1
	Renal and urinary disorders/ Pollakiuria/ URINARY FREQUENCY	10JUL2012 /5	24JUL2012 /-35	I	1	1	1	3	1
	General disorders and administration site conditions/ Injection site pain/ SITE INJECTION TENDERNESS	05JUL2012 /0	06JUL2012 /-53	C	1	0	1	1	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea exertional/ DYSPNEA ON EXERTION	11JUL2012 /6	17JUL2012 /-42	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0030/51 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	10JUL2012 /5	05OCT2012 /38	I	1	0	1	2	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	21AUG2012 /47	28AUG2012 /0	I	1	0	1	2	1
101-0032/84 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ EDEMA-LIMBS	09AUG2012 /8	27AUG2012 /-43	C	3	1	1	5	1
	General disorders and administration site conditions/ Injection site erythema/ MILD REDNESS AT INJECTION SITE	01AUG2012 /0	08AUG2012 /-62	I	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0032/84 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ EDEMA-LIMBS	03SEP2012 /33	13SEP2012 /-26	I	1	1	3 /04SEP2012 /14SEP2012	5	3
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA-LIMBS	27AUG2012 /26	03SEP2012 /-36	C	3	1	1	5	2
	General disorders and administration site conditions/ Injection site erythema/ MILD REDNESS AT INJECTION SITE	22AUG2012 /21	13SEP2012 /-26	I	1	1	1	2	1
101-0033/66 /F/W2/N	Eye disorders/ Dry eye/ DRY EYE	04AUG2012 /1	16AUG2012 /-141	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0033/66 /F/W2/N	Psychiatric disorders/ Anxiety/ ANXIETY	08DEC2012 /127	20DEC2012 /-15	I	1	0	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	25AUG2012 /22	26AUG2012 /-131	I	1	0	1	3	1
101-0036/68 /M/A4/N	General disorders and administration site conditions/ Influenza like illness/ FLU-LIKE SYMPTOMS	04JAN2013 /59	18JAN2013 /52	C	1	0	1	5	1
	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINEMIA	04JAN2013 /59	18JAN2013 /52	C	1	0	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0038/56 /M/W2/N	Investigations/ Blood uric acid increased/ ELEVATED URIC ACID	01MAR2013 /24	06MAR2013 /-6	I	1	1	1	5	1
	Nervous system disorders/ Encephalopathy/ ENCEPHALOPATHY	12MAR2013 /35	12APR2013 /31	I	3	1	2	4	1
101-0039/77 /F/W2/N	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	30DEC2013 /269	06JAN2014 /42	C	1	0	1	3	3
	General disorders and administration site conditions/ Injection site irritation/ IRRITATION AT INJECTION SITE	19APR2013 /14	26APR2013 /-213	C	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0039/77 /F/W2/N	Skin and subcutaneous tissue disorders/ Rash/ RASH (ABDOMEN)	14JUN2013 /70	21JUN2013 /-157	C	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRITIC JOINT PAIN	02JUL2013 /88	Unknown/NA	I	6	1	1	4	1
	Psychiatric disorders/ Anxiety/ ANXIETY	18NOV2013 /227	18NOV2013 /-7	I	1	0	1	5	1
	Nervous system disorders/ Headache/ HEADACHE	10JUL2013 /96	16JUL2013 /-132	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0040/60 /M/W2/N	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastatic pain/ NON-CARDIAC CHEST PAIN 2/2 BONE METASTASIS	05AUG2013 /35	Unknown/NA	I	6	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISM	06AUG2013 /36	Unknown/NA	C	6	1	1	4	3
101-0041/54 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	27AUG2013 /28	10SEP2013 /35	C	1	0	1	4	3
	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINEMIA	10SEP2013 /42	23SEP2013 /48	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0041/54 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ LOWER EXTREMITY EDEMA	10SEP2013 /42	23SEP2013 /48	C	1	0	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	12AUG2013 /13	16AUG2013 /10	C	1	1	2	3	3
101-0042/64 /M/W2/N	Nervous system disorders/ Encephalopathy/ ENCEPHALOPATHY	10SEP2013 /36	23SEP2013 /20	C	1	1	2	3	3
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	15AUG2013 /10	18AUG2013 /-16	C	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0042/64 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	20AUG2013 /15	03SEP2013 /0	C	1	0	1	2	1
101-0044/78 /M/W2/Y	Gastrointestinal disorders/ Ascites/ ASCITES	17JAN2014 /91	Unknown/NA	I	6	1	1	5	2
	Metabolism and nutrition disorders/ Hypophosphataemia/ HYPOPHOSPHATEMIA	23JAN2014 /97	23JAN2014 /27	C	1	1	1	5	3
	Nervous system disorders/ Dizziness/ DIZZINESS	06DEC2013 /49	20DEC2013 /-7	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0044/78 /M/W2/Y	Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GASTRIC REFLUX	08NOV2013 /21	15NOV2013 /-42	C	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	21JAN2014 /95	Unknown/NA	I	6	1	1	5	1
	Gastrointestinal disorders/ Ascites/ ASCITES	06DEC2013 /49	20DEC2013 /-7	C	1	1	1	4	1
	Gastrointestinal disorders/ Haemorrhoids/ HEMORRHOIDS	17JAN2014 /91	Unknown/NA	I	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0044/78 /M/W2/Y	Eye disorders/ Conjunctival haemorrhage/ CONJUNCTIVAL HEMORRHAGE (LEFT)	11JAN2014 /85	17JAN2014 /21	C	1	0	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	11JAN2014 /85	17JAN2014 /21	C	1	0	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Pharyngeal inflammation/ PHARYNGEAL MUCOSITIS	20JAN2014 /94	25JAN2014 /29	C	1	1	1	5[This Is Considered Definitely Related To The Patient's New Treatment Of Doxorubicin Plus Sorafenib.]	3
	General disorders and administration site conditions/ Oedema peripheral/ LOWER EXTREMITY EDEMA	31JAN2014 /105	07FEB2014 /42	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0044/78 /M/W2/Y	General disorders and administration site conditions/ Fatigue/ FATIGUE	18OCT2013 /0	Unknown/NA	I	6	0	1	5	1
	Infections and infestations/ Otitis media acute/ ACUTE OTITIS MEDIA	01NOV2013 /14	06DEC2013 /-21	C	1	1	1	5	2
	Nervous system disorders/ Headache/ HEADACHE	11JAN2014 /85	20JAN2014 /24	C	1	0	1	5	2
	Nervous system disorders/ Syncope/ SYNCOPE	21JAN2014 /95	21JAN2014 /25	C	1	0	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0044/78 /M/W2/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	17JAN2014 /91	20JAN2014 /24	C	1	0	1	5	1
	Gastrointestinal disorders/ Stomatitis/ ORAL MUCOSITIS	20JAN2014 /94	25JAN2014 /29	C	1	1	1	5[This Is Considered Definitely Related To The Patient's New Treatment Of Doxorubicin Plus Sorafenib.]	3
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	17JAN2014 /91	Unknown/NA	I	6	1	1	5	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	04DEC2013 /47	27DEC2013 /0	C	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0044/78 /M/W2/Y	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	06DEC2013 /49	20DEC2013 /-7	C	1	0	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	11JAN2014 /85	20JAN2014 /24	I	1	0	1	5	1
	Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	21JAN2014 /95	23JAN2014 /27	C	1	1	1	5	3
101-0045/74 /F/W2/N	General disorders and administration site conditions/ Pain/ PAIN (GENERALIZED)	19NOV2013 /15	26NOV2013 /-49	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0045/74 /F/W2/N	Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GERD	04NOV2013* /0	Unknown/NA	I	6	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	22JAN2014 /79	03FEB2014 /20	I	3	0	1	5	1
	Nervous system disorders/ Encephalopathy/ ENCEPHALOPATHY	07FEB2014 /95	Unknown/NA	C	6	1	1	5 [PD]	2
	General disorders and administration site conditions/ Gait disturbance/ GAIT INSTABILITY	12NOV2013 /8	19NOV2013 /-56	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0045/74 /F/W2/N	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIGHT SHOULDER PAIN	07JAN2014 /64	21JAN2014 /7	C	1	1	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	10DEC2013 /36	31DEC2013 /-14	C	1	0	1	3	1
	Metabolism and nutrition disorders/ Hypophosphataemia/ HYPOPHOSPHATEMIA	03FEB2014 /91	Unknown/NA	C	6	0	1	5	2
	Psychiatric disorders/ Depression/ DEPRESSION	03FEB2014 /91	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0045/74 /F/W2/N	Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIA	26NOV2013 /22	26NOV2013 /-49	C	1	0	1	5	3
	Nervous system disorders/ Headache/ HEADACHE	12NOV2013 /8	19NOV2013 /-56	C	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	03FEB2014 /91	Unknown/NA	I	6	0	1	5	2
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ PAIN (RT SHOULDER)	07JAN2014 /64	21JAN2014 /7	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0046/70 /M/OTH/N	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	04FEB2014 /105	11FEB2014 /42	C	1	0	1	3	3
	Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE SPASM	23DEC2013 /62	31DEC2013 /0	I	1	1	1	4	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	23DEC2013 /62	31DEC2013 /0	C	1	0	1	4	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	22OCT2013 /0	Unknown/NA	I	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0046/70 /M/OTH/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	24DEC2013 /63	31DEC2013 /0	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Hypophosphataemia/ HYPOPHOSPHATEMIA	12NOV2013 /21	07JAN2014 /7	C	1	1	1	4	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	23OCT2013 /1	28OCT2013 /-64	I	1	0	1	3	1
101-0047/52 /M/W2/N	Gastrointestinal disorders/ Stomatitis/ MOUTH SORES	09DEC2013 /48	16DEC2013 /7	C	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0047/52 /M/W2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	25OCT2013 /3	28OCT2013 /-42	I	1	0	1	3	2
	Hepatobiliary disorders/ Cholangitis acute/ ACUTE CHOLANGITIS	11DEC2013 /50	23DEC2013 /14	C	1	1	3 /16DEC2013 /Unknown	5[PD]	3
	General disorders and administration site conditions/ Fatigue/ WORSENER FATIGUE	30DEC2013 /69	06JAN2014 /28	C	1	0	1	3	2
101-0048/66 /F/W2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	23OCT2013 /1	19NOV2013 /-41	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0048/66 /F/W2/N	General disorders and administration site conditions/ Oedema peripheral/ LEFT LOWER EXTREMITY EDEMA	19NOV2013 /28	25NOV2013 /-35	C	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	23DEC2013 /62	06JAN2014 /7	I	1	0	1	2	1
101-0049/71 /M/A8/N	Skin and subcutaneous tissue disorders/ Rash pruritic/ PRURITIC RASH	02DEC2013 /35	09DEC2013 /-28	C	1	0	1	3	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	28OCT2013 /0	Unknown/NA	I	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0049/71 /M/A8/N	Cardiac disorders/ Tachycardia/ TACHYCARDIA	25NOV2013 /28	09DEC2013 /-28	I	1	0	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	02DEC2013 /35	30DEC2013 /-7	C	1	2	3 /02DEC2013 /09DEC2013	4	2
101-0050/59 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	25NOV2013 /27	30DEC2013 /28	C	1	0	1	5	2
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	18NOV2013 /20	25NOV2013 /-7	C	1	0	3 /18NOV2013 /25NOV2013	2	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0050/59 /M/W2/N	Gastrointestinal disorders/ Dysphagia/ DYSPHAGIA	17DEC2013 /49	Unknown/NA	I	6	0	1	5	2
	Psychiatric disorders/ Depression/ DEPRESSION	17DEC2013 /49	Unknown/NA	C	6	1	1	5	1
	Gastrointestinal disorders/ Dry mouth/ DRY MOUTH	12NOV2013 /14	18NOV2013 /-14	I	1	0	1	5	1
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	18NOV2013 /20	25NOV2013 /-7	C	1	0	3 /18NOV2013 /25NOV2013	2	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0050/59 /M/W2/N	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	02DEC2013 /34	10DEC2013 /8	C	1	0	1	3	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	18NOV2013 /20	25NOV2013 /-7	C	1	0	3 /18NOV2013 /25NOV2013	2	3
102-0001/53 /M/BL/N	Investigations/ Aspartate aminotransferase increased/ HIGH AST	15MAY2012 /20	09NOV2012 /157	C	1	0	1	3	3
	Nervous system disorders/ Headache/ HEADACHE (RT SIDE; ABOVE RT EAR)	29MAY2012 /34	29MAY2012 /-7	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
102-0001/53 /M/BL/N	Ear and labyrinth disorders/ Tinnitus/ AUDITORY - OTHER (HIGH PITCHED SOUNDS HEAR 1-2 TIMES DAILY	12JUN2012 /48	09NOV2012 /157	I	1	0	1	4	1
	Investigations/ Blood alkaline phosphatase increased/ HIGH ALKALINE PHOSPHATASE	15MAY2012 /20	09NOV2012 /157	C	1	0	1	3	3
	Skin and subcutaneous tissue disorders/ Night sweats/ NIGHT SWEATS	29MAY2012 /34	29MAY2012 /-7	I	1	0	1	4	1
102-0003/63 /M/BL/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	07NOV2012 /56	14NOV2012 /-14	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
102-0003/63 /M/BL/N	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	28NOV2012 /77	25JAN2013 /58	I	1	0	1	4	3
	Gastrointestinal disorders/ Abdominal pain/ PAIN (ABDOMINAL)	26SEP2012 /14	25JAN2013 /58	I	1	1	1	4	2
	Investigations/ Prothrombin time prolonged/ HIGH PROTHROMBIN TIME (PT)	19SEP2012 /7	25JAN2013 /58	C	1	0	1	4	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	17SEP2012 /5	25JAN2013 /58	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
102-0003/63 /M/BL/N	Investigations/ Blood lactate dehydrogenase increased/ HIGH LDH	19SEP2012 /7	25JAN2013 /58	C	1	0	1	3	1
	Investigations/ Platelet count increased/ HIGH PLATELETS	17OCT2012 /35	25JAN2013 /58	C	1	0	1	4	1
	Investigations/ International normalised ratio increased/ INR INCREASED	28NOV2012 /77	25JAN2013 /58	I	1	0	1	4	1
	Investigations/ Haematocrit decreased/ LOW HEMATOCRIT	28NOV2012 /77	25JAN2013 /58	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
102-0003/63 /M/BL/N	Investigations/ Blood albumin decreased/ LOW ALBUMIN	03OCT2012 /21	25JAN2013 /58	C	1	0	1	4	1
	Investigations/ Protein total increased/ HIGH TOTAL PROTEIN	19SEP2012 /7	25JAN2013 /58	C	1	0	1	4	1
	Investigations/ Blood uric acid increased/ HIGH URIC ACID	10OCT2012 /28	25JAN2013 /58	C	1	0	1	4	1
	Investigations/ Bilirubin conjugated increased/ HIGH DIRECT BILIRUBIN	03OCT2012 /21	25JAN2013 /58	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
102-0003/63 /M/BL/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	17SEP2012 /5	25JAN2013 /58	C	1	0	1	4	2
102-0008/64 /M/BL/N	Renal and urinary disorders/ Haematuria/ HEMATURIA	09FEB2014 /32	10FEB2014 /5	C	1	0	1	4	1
	Cardiac disorders/ Cardiac arrest/ CARDIAC ARREST	09FEB2014 /32	10FEB2014 /5	C	4	0	2	4[Cardiac - Other]	5
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA (BILATERAL EXTREMITIES)	08JAN2014 /0	10FEB2014 /5	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
102-0008/64 /M/BL/N	Gastrointestinal disorders/ Abdominal pain/ PAIN (UPPER ABDOMEN)	15JAN2014 /7	10FEB2014 /5	I	1	0	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA (GRADE 1)	15JAN2014 /7	10FEB2014 /5	I	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Clubbing/ CLUBBING (EXTREMITIES)	08JAN2014 /0	10FEB2014 /5	C	1	0	1	5	1
	Investigations/ Haemoglobin decreased/ HEMOGLOBIN - LOW (GRADE 2; ALSO PRESENT AT BASELINE)	23JAN2014 /15	10FEB2014 /5	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
102-0009/58 /M/W2/N	Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	12NOV2014 /14	12NOV2014 /-28	I	1	2	1	3	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	05NOV2014 /7	04FEB2015 /56	C	1	0	1	3	1
	Injury, poisoning and procedural complications/ Fall/ FALL	26NOV2014 /28	26NOV2014 /-14	I	2	0	1	4	1
	Injury, poisoning and procedural complications/ Skin abrasion/ ABRASION (LEFT EYEBROW, RIGHT KNEE)	26NOV2014 /28	26NOV2014 /-14	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
102-0009/58 /M/W2/N	Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	03DEC2014 /35	03DEC2014 /-7	I	1	1	1	3	2
	Skin and subcutaneous tissue disorders/ Rash macular/ RASH (CHEST; MACULAR)	29OCT2014 /0	04FEB2015 /56	C	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ PAIN (ABDOMINAL)	29OCT2014 /0	05NOV2014 /-35	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	08NOV2014 /10	08NOV2014 /-32	I	1	2	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
102-0009/58 /M/W2/N	Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES	19NOV2014 /21	19NOV2014 /-21	I	1	0	1	2	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	03DEC2014 /35	04FEB2015 /56	C	1	1	1	3	1
	General disorders and administration site conditions/ Non-cardiac chest pain/ PAIN (CHEST - NON-CARDIAC)	08NOV2014 /10	04FEB2015 /56	C	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Muscular weakness/ MUSCLE WEAKNESS (LOWER EXTREMITY)	17DEC2014 /49	04FEB2015 /56	C	1	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
102-0009/58 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ EDEMA (LEG)	29OCT2014 /0	05NOV2014 /-35	I	1	0	1	5	1
103-0001/56 /M/W2/N	Musculoskeletal and connective tissue disorders/ Neck pain/ PAIN IN NECK	15AUG2012 /96	Unknown/NA	C	2	1	1	4	2
	Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIA	01JUN2012 /21	29JUN2012 /-21	C	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING	17JUL2012 /67	17JUL2012 /-3	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
103-0001/56 /M/W2/N	Injury, poisoning and procedural complications/ Contusion/ MINOR BRUISING ON SKIN	05JUN2012 /25	01AUG2012 /12	C	1	0	1	4	1
	Musculoskeletal and connective tissue disorders/ Neck pain/ PAIN IN NECK	24JUN2012 /44	06JUL2012 /-14	C	1	0	1	5	1
103-0003/66 /M/W2/N	Gastrointestinal disorders/ Abdominal pain/ PAIN (RIGHT SIDED/ABDOMINAL)	18JUN2013 /123	Unknown/NA	I	6	0	1	4	1
	Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIA	04APR2013 /48	17APR2013 /-92	C	1	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
103-0003/66 /M/W2/N	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBNEMIA	04APR2013 /48	17APR2013 /-92	C	1	0	1	4	2
	Nervous system disorders/ Dysgeusia/ METALIC TASTE	15FEB2013 /0	15FEB2013 /-153	C	1	0	1	3	1
	Metabolism and nutrition disorders/ Fluid retention/ WATER RETENTION	11APR2013 /55	Unknown/NA	C	6	1	1	4	2
	General disorders and administration site conditions/ Pain/ PAIN (RIGHT SIDED)	10JUN2013 /115	12JUN2013 /-36	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
103-0004/40 /F/A1/Y	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RT SHOULDER PAIN	02JUN2014 /42	Unknown/NA	C	6	3	1	5	2
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	13MAY2014 /22	18MAY2014 /-15	C	1	0	1	2	2
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ RT ARM PAIN	02JUN2014 /42	Unknown/NA	C	6	1	1	5	2
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	19MAY2014 /28	02JUN2014 /0	C	1	1	3 /19MAY2014 /02JUN2014	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
103-0004/40 /F/A1/Y	Investigations/ Lymphocyte count decreased/ DECREASED LYMPHOCYTES	27MAY2014 /36	08JUN2014 /6	C	1	0	1	3	3
	Musculoskeletal and connective tissue disorders/ Muscular weakness/ RT ARM WEAKNESS	02JUN2014 /42	Unknown/NA	C	6	1	1	5	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	28APR2014 /7	02JUN2014 /0	I	1	1	1	3	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	27MAY2014 /36	01JUN2014 /-1	C	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
104-0003/56 /F/W2/N	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHY PALMS	10AUG2012 /22	10AUG2012 /-19	C	1	0	1	3	1
	Nervous system disorders/ Hypoaesthesia/ NUMBNESS (FINGERTIP)	03AUG2012 /15	03AUG2012 /-26	C	1	0	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ NON-PRODUCTIVE COUGH	06SEP2012 /49	Unknown/NA	C	6	0	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	21AUG2012 /33	21AUG2012 /-8	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
104-0003/56 /F/W2/N	General disorders and administration site conditions/ Injection site pruritus/ INJECTION REACTION (PRURITIS)	01AUG2012 /13	08AUG2012 /-21	C	1	1	1	3	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	27AUG2012 /39	Unknown/NA	C	6	1	1	3	2
	General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	08AUG2012 /20	08AUG2012 /-21	I	1	0	1	3	1
	Blood and lymphatic system disorders/ Lymphadenopathy/ GROIN LYMPHADENOPATHY	15AUG2012 /27	27AUG2012 /-2	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
104-0004/74 /M/W2/Y	General disorders and administration site conditions/ Peripheral swelling/ LEG/ANKLE SWELLING	05DEC2012 /40	24MAY2013 /199	C	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ LFT SHOULDER PAIN	07NOV2012 /12	24MAY2013 /199	C	1	0	1	5	1
104-0008/55 /M/PI/N	Skin and subcutaneous tissue disorders/ Skin hypertrophy/ RT THIRD FINGER (MEDIAL ASPECT) WITH LINEAR SHAPE SKIN THICKENING, SCALY AND DRY, <2CM	25OCT2013 /52	02DEC2013 /10	I	1	0	1	4	1
	Cardiac disorders/ Sinus bradycardia/ SINUS BRADYCARDIA	03SEP2013 /0	03SEP2013 /-80	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
104-0008/55 /M/PI/N	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	15NOV2013 /73	Unknown/NA	C	6	0	1	3	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	27SEP2013 /24	Unknown/NA	C	6	0	1	3	2
	Nervous system disorders/ Dysgeusia/ CHANGE IN TASTE	15NOV2013 /73	Unknown/NA	C	6	0	1	2	1
104-0010/71 /F/A8/N	Eye disorders/ Visual impairment/ RIGHT SIDED VISUAL CHANGES	29MAR2014 /80	Unknown/NA	C	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
104-0010/71 /F/A8/N	Investigations/ Blood uric acid increased/ ELEVATED URIC ACID	22JAN2014 /14	05FEB2014 /-224	C	1	1	1	2	1
	Nervous system disorders/ Dizziness/ DIZZINESS	01MAR2014 /52	01MAR2014 /-200	C	2	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ CHRONIC RT SCAPULAR MUSCLE PAIN	19MAR2014 /70	Unknown/NA	C	6	1	1	4	1
	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	02JUL2014 /175	30JUL2014 /-49	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
104-0010/71 /F/A8/N	Nervous system disorders/ Headache/ HEADACHES	29MAR2014 /80	Unknown/NA	I	6	0	1	4	1
104-0012/78 /F/A2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	29NOV2014 /58	02DEC2014 /8	I	1	1	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS ON UPPER BODY	14OCT2014 /12	Unknown/NA	I	6	0	1	4	1
	General disorders and administration site conditions/ Injection site pain/ PAIN AT THE INJECTION SITE	13OCT2014 /11	02DEC2014 /8	I	1	0	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
104-0012/78 /F/A2/N	Musculoskeletal and connective tissue disorders/ Back pain/ UPPER BACK PAIN	17OCT2014 /15	Unknown/NA	I	6	1	1	4	1
	General disorders and administration site conditions/ Oedema/ EDEMA	21OCT2014 /19	Unknown/NA	C	6	0	1	4	1
106-0001/42 /F/W2/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	06JUN2012 /93	Unknown/NA	I	6	1	1	4	2
	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	18JUN2012 /105	25JUN2012 /0	C	1	3	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
106-0001/42 /F/W2/N	Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	29JUN2012 /116	01JUL2012 /6	C	1	1	1	5 [PD]	3
	Metabolism and nutrition disorders/ Diabetes mellitus/ DIABETES	19MAR2012 /14	Unknown/NA	I	6	1	1	5 [CD]	4
	General disorders and administration site conditions/ Infusion site rash/ LOCALIZED RASH (LOCAL INFUSION REACTION)	14MAY2012 /70	14MAY2012 /-42	I	1	1	1	3	2
	Gastrointestinal disorders/ Dyspepsia/ EPIGASTRIC BURNING	06JUN2012 /93	Unknown/NA	I	6	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
106-0001/42 /F/W2/N	Blood and lymphatic system disorders/ Anaemia/ WORSENING ANEMIA	29JUN2012 /116	01JUL2012 /6	C	1	2	1	4 [PD]	3
107-0002/71 /M/W2/N	Infections and infestations/ Cellulitis/ CELLULITIS LEFT LOWER EXTREMITY	12SEP2012 /16	21SEP2012 /-45	C	1	1	3 /12SEP2012 /21SEP2012	5	3
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	10OCT2012 /44	16OCT2012 /-20	I	1	1	1	5	1
	Gastrointestinal disorders/ Stomatitis/ MUCOSITIS MOUTH	05DEC2012 /100	06FEB2013 /93	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
107-0002/71 /M/W2/N	Infections and infestations/ Cellulitis/ CELLULITIS LEFT LOWER EXTREMITY	03SEP2012 /7	12SEP2012 /-54	C	3	1	1	5	1
	Nervous system disorders/ Dizziness/ INTERMITTENT DIZZINESS	11OCT2012 /45	22OCT2012 /-14	I	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ BILATERAL SHOULDER PAIN	05NOV2012 /70	12NOV2012 /7	I	1	0	1	5	1
	Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	11OCT2012 /45	16OCT2012 /-20	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
107-0002/71 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	15OCT2012 /49	22OCT2012 /-14	I	1	0	1	5	2
107-0003/73 /M/BL/N	General disorders and administration site conditions/ Disease progression/ HEPATOMA, PROGRESSIVE	31MAR2013 /34	03APR2013 /-20	I	1	1	3 /01APR2013 /16APR2013	5[CD]	3
	Cardiac disorders/ Angina pectoris/ CARDIAC CHEST PAINS	30MAR2013 /33	03APR2013 /-20	I	1	1	1	5[CD]	3
	General disorders and administration site conditions/ Peripheral swelling/ LOWER EXTREMITY SWELLING	19APR2013 /53	Unknown/NA	I	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
107-0003/73 /M/BL/N	Skin and subcutaneous tissue disorders/ Dry skin/ DRY SKIN	04APR2013 /38	Unknown/NA	I	6	0	1	5	2
	Cardiac disorders/ Angina pectoris/ ANGINA PECTORIS	04APR2013 /38	Unknown/NA	I	6	1	1	5	1
	Infections and infestations/ Sinusitis/ SINUSITIS	23APR2013 /57	Unknown/NA	C	6	0	1	5	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	26APR2013 /60	27APR2013 /4	C	1	2	1	5 [CD]	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
107-0003/73 /M/BL/N	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITIS	04APR2013 /38	Unknown/NA	I	6	1	1	5	2
	Gastrointestinal disorders/ Ascites/ ASCITES	19APR2013 /53	Unknown/NA	C	6	1	1	5	2
107-0004/63 /M/W2/N	General disorders and administration site conditions/ Injection site pain/ RIGHT UPPER ARM SORENESS AT INJECTION SITE	13MAR2013 /9	19MAR2013 /-56	I	1	0	1	2	1
	General disorders and administration site conditions/ Injection site pain/ RIGHT UPPER ARM SORENESS AT INJECTION SITE	26MAR2013 /22	02APR2013 /-42	I	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
107-0006/60 /M/W2/N	General disorders and administration site conditions/ Temperature intolerance/ COLD INTOLERANCE	17JUN2013 /34	01JUL2013 /-22	C	1	0	1	3	1
	General disorders and administration site conditions/ Injection site erythema/ REDNESS BILATERAL UPPER ARMS AT INJECTION SITE	18JUN2013 /35	08JUL2013 /-15	C	1	0	1	3	1
	General disorders and administration site conditions/ Injection site erythema/ REDNESS BILATERAL UPPER ARMS AT INJECTION SITE	28MAY2013 /14	04JUN2013 /-49	C	1	0	1	3	1
	General disorders and administration site conditions/ Injection site erythema/ FAINT ERYTHEMA LEFT UPPER ARM AT INJECTION SITE 2 CM	19AUG2013 /97	16SEP2013 /55	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
107-0006/60 /M/W2/N	General disorders and administration site conditions/ Injection site rash/ RASH BILATERAL UPPER ARMS AT INJECTION SITE	29JUL2013 /76	19AUG2013 /27	C	1	0	1	3	1
	General disorders and administration site conditions/ Injection site erythema/ REDNESS BILATERAL UPPER ARMS AT INJECTION SITE	29JUL2013 /76	16AUG2013 /24	C	1	0	1	3	1
108-0001/60 /F/W2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	21MAR2012 /0	Unknown/NA	I	6	1	1	4	1
	Gastrointestinal disorders/ Dysphagia/ DYSPHAGIA	21APR2012 /31	Unknown/NA	C	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
108-0001/60 /F/W2/N	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	03APR2012 /13	Unknown/NA	C	6	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ THROAT PAIN	21APR2012 /31	Unknown/NA	C	6	0	1	5	2
108-0002/78 /M/BL/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	02JUN2012 /2	03JUN2012 /-32	C	1	1	1	4	1
108-0004/61 /M/W2/N	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	16MAY2013 /28	22MAY2013 /13	C	1	1	3 /16MAY2013 /Unknown	4[CD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
108-0004/61 /M/W2/N	Gastrointestinal disorders/ Vomiting/ VOMITING	06MAY2013 /18	17MAY2013 /8	I	1	1	1	4	2
	Psychiatric disorders/ Anxiety/ ANXIETY	22MAY2013 /34	Unknown/NA	C	6	1	1	4	2
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	22MAY2013 /34	Unknown/NA	I	6	1	1	4	2
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	23APR2013 /5	26APR2013 /-13	C	1	1	1	4 [CD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
108-0004/61 /M/W2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	06MAY2013 /18	17MAY2013 /8	I	1	1	1	4	2
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	12MAY2013 /24	14MAY2013 /5	C	1	1	1	4 [CD]	2
108-0005/68 /M/W2/N	Gastrointestinal disorders/ Varices oesophageal/ ESOPHAGEL VARICES	24JUN2013 /47	24JUN2013 /-23	C	1	3	1	4	3
	Gastrointestinal disorders/ Gastric varices/ GASTRIC VARICES	17MAY2013 /9	Unknown/NA	C	6	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
108-0005/68 /M/W2/N	Skin and subcutaneous tissue disorders/ Scab/ SCABS ON FOREARMS AND HANDS	15MAY2013 /7	Unknown/NA	C	6	0	1	4	1
	Gastrointestinal disorders/ Varices oesophageal/ ESOPHAGEAL VARICES	15MAY2013 /7	17MAY2013 /-61	C	1	1	1	4	3
	Gastrointestinal disorders/ Nausea/ NAUSEA	18JUN2013 /41	Unknown/NA	C	6	0	1	4	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	26JUN2013 /49	Unknown/NA	C	6	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
108-0005/68 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Rales/ MILD BIBASILAR INSPIRATORY CRACKLES	12JUN2013 /35	18JUN2013 /-29	C	1	0	1	4	1
	Investigations/ Haemoglobin decreased/ DECREASED HEMOGLOBIN	15MAY2013 /7	22MAY2013 /-56	C	1	2	1	4	3
108-0008/77 /M/W2/N	Skin and subcutaneous tissue disorders/ Eczema nummular/ NUMMULAR ECZEMA	23DEC2014 /75	08JAN2015 /-56	C	1	1	1	3	1
	Skin and subcutaneous tissue disorders/ Eczema nummular/ NUMMULAR ECZEMA	13NOV2014 /35	20NOV2014 /-105	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
108-0008/77 /M/W2/N	Psychiatric disorders/ Agitation/ AGITATION	16OCT2014 /7	16OCT2014 /-140	I	1	0	1	4	2
	Skin and subcutaneous tissue disorders/ Eczema nummular/ NUMMULAR ECZEMA	27NOV2014 /49	18DEC2014 /-77	C	1	1	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	04DEC2014 /56	Unknown/NA	I	6	0	1	4	1
	Gastrointestinal disorders/ Abdominal pain/ WORSENING PAIN (ABDOMEN)	08MAR2015 /150	11MAR2015 /6	C	1	1	1	5 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
108-0008/77 /M/W2/N	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	16OCT2014 /7	Unknown/NA	C	6	0	1	4	1
	Skin and subcutaneous tissue disorders/ Eczema nummular/ NUMULAR ECZEMA	21OCT2014 /12	30OCT2014 /-126	C	1	0	1	3	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN (WORSENING)	18DEC2014 /70	08MAR2015 /3	C	1	1	1	5	2
	Gastrointestinal disorders/ Abdominal pain/ WORSENING ABDOMINAL PAIN	11MAR2015 /153	Unknown/NA	C	6	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
108-0008/77 /M/W2/N	Skin and subcutaneous tissue disorders/ Eczema nummular/ NUMMULAR ECZEMA	05MAR2015 /147	Unknown/NA	C	6	1	1	3	1
	Skin and subcutaneous tissue disorders/ Eczema nummular/ NUMMULAR ECZEMA	19FEB2015 /133	26FEB2015 /-7	C	1	1	1	3	1
	Skin and subcutaneous tissue disorders/ Dry skin/ DRY SKIN	30OCT2014 /21	Unknown/NA	C	6	0	1	4	1
	Skin and subcutaneous tissue disorders/ Eczema nummular/ NUMMULAR ECZEMA	22JAN2015 /105	05FEB2015 /-28	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
108-0008/77 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	30OCT2014 /21	Unknown/NA	C	6	0	1	4	1
109-0003/68 /M/W2/N	Skin and subcutaneous tissue disorders/ Rash/ RASH (LEFT PECTORAL)	20MAY2013 /14	17JUN2013 /-14	C	1	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE (WORSENING FROM BASELINE)	02JUN2013 /27	Unknown/NA	C	6	0	1	5	2
	Investigations/ Aspartate aminotransferase increased/ ELEVATED AST	28MAY2013 /22	10JUN2013 /-21	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0003/68 /M/W2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	01JUN2013 /26	Unknown/NA	I	6	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	22MAY2013 /16	Unknown/NA	C	6	0	1	5	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	23JUN2013 /48	Unknown/NA	C	6	1	1	5	1
	Gastrointestinal disorders/ Dry mouth/ DRY MOUTH	01JUN2013 /26	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0003/68 /M/W2/N	Psychiatric disorders/ Anxiety/ ANXIETY	01JUN2013 /26	Unknown/NA	C	6	1	1	5	1
	Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	23MAY2013 /17	01JUN2013 /-30	C	1	1	1	5	2
	Gastrointestinal disorders/ Nausea/ NAUSEA (WORSENING FROM BASELINE)	28MAY2013 /22	Unknown/NA	I	6	1	1	5	2
	Investigations/ Aspartate aminotransferase increased/ ELEVATED AST	10JUN2013 /35	Unknown/NA	C	6	0	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0003/68 /M/W2/N	Hepatobiliary disorders/ Hyperbilirubinaemia/ BILIRUBINEMIA	10JUN2013 /35	Unknown/NA	C	6	0	1	5	2
109-0004/57 /M/W2/N	Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	19JUL2013 /0	19JUL2013 /-76	I	1	0	1	5	1
109-0006/62 /M/PI/N	Gastrointestinal disorders/ Abdominal pain/ PAIN (RIGHT MIDDLE QUADRANT)	03OCT2013 /41	Unknown/NA	I	6	0	1	5	1
	Injury, poisoning and procedural complications/ Post-traumatic pain/ PAIN (R SHIN DUE TO TRAUMA)	09SEP2013 /17	Unknown/NA	C	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0006/62 /M/PI/N	Gastrointestinal disorders/ Stomatitis/ MUCOSITIS (ORAL)	30AUG2013 /7	Unknown/NA	C	6	0	1	4	1
	Injury, poisoning and procedural complications/ Lower limb fracture/ FRACTURE - RIGHT LEG	09SEP2013 /17	Unknown/NA	C	6	1	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	30AUG2013 /7	Unknown/NA	C	6	0	1	3	1
	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	20NOV2013 /89	31JAN2014* /93	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0007/55 /M/W2/N	Renal and urinary disorders/ Renal colic/ RENAL COLIC	17JAN2014 /38	18JAN2014 /-87	C	1	1	3 /17JAN2014 /24JAN2014	4[CD]	3
	Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	17JAN2014 /38	21MAY2014 /36	C	1	1	3 /17JAN2014 /24JAN2014	4[CD]	3
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	17JAN2014 /38	23APR2014 /8	C	1	1	3 /17JAN2014 /24JAN2014	4[CD]	2
	Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA - BILATERAL HIPS	25MAR2014 /105	Unknown/NA	C	6	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0007/55 /M/W2/N	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	01JAN2014* /22	Unknown/NA	C	6	0	1	4	1
	Cardiac disorders/ Left ventricular dysfunction/ LEFT VENTRICULAR SYSTOLIC DYSFUNCTION	17JAN2014 /38	Unknown/NA	I	6	0	3 /17JAN2014 /24JAN2014	4 [CD]	3
	Vascular disorders/ Hot flush/ HOT FLASHES	12MAR2014 /92	Unknown/NA	C	6	0	1	3	1
	Cardiac disorders/ Mitral valve disease/ MITRAL VALVE DISEASE	17JAN2014 /38	Unknown/NA	C	6	1	3 /17JAN2014 /24JAN2014	4 [CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0007/55 /M/W2/N	Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA - BILATERAL SHOULDERS	01JAN2014* /22	Unknown/NA	C	6	0	1	3	2
	Renal and urinary disorders/ Urinary tract pain/ PAIN - URINARY TRACT	16JAN2014 /37	18JAN2014 /-87	C	1	0	1	5	2
	General disorders and administration site conditions/ Injection site reaction/ INJECTION SITE REACTION	04MAR2014 /84	09MAR2014 /-37	C	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Polymyalgia rheumatica/ POLYMYALGIA RHEUMATICA	08APR2014 /119	Unknown/NA	C	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0007/55 /M/W2/N	Investigations/ Ejection fraction decreased/ EJECTION FRACTION DECREASED	17JAN2014 /38	Unknown/NA	C	6	1	3 /17JAN2014 /24JAN2014	4 [CD]	3
	Renal and urinary disorders/ Pollakiuria/ URINARY FREQUENCY	16JAN2014 /37	18JAN2014 /-87	C	1	0	1	5	1
	Renal and urinary disorders/ Urinary tract obstruction/ URINARY TRACT OBSTRUCTION	17JAN2014 /38	18JAN2014 /-87	C	1	1	3 /17JAN2014 /24JAN2014	4[Urinary Tract Obstruction , Causing Anxiety And Pain, Exacerbatin g Underlying Cardiac Symptoms]	3
	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINEMIA	28JAN2014 /49	26FEB2014 /-48	C	1	0	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0007/55 /M/W2/N	General disorders and administration site conditions/ Non-cardiac chest pain/ NON-CARDIAC CHEST PAIN	26FEB2014 /78	Unknown/NA	C	6	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Flank pain/ PAIN - LATERAL FLANK	14JAN2014 /35	18JAN2014 /-87	C	1	1	1	5	2
109-0008/70 /F/W2/Y	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	09JUL2014 /35	08AUG2014 /-97	C	1	0	1	5	1
	General disorders and administration site conditions/ Injection site reaction/ INJECTION SITE REACTION	08AUG2014 /65	Unknown/NA	I	6	0	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0008/70 /F/W2/Y	General disorders and administration site conditions/ Malaise/ MALAISE	26JUN2014 /22	17DEC2014 /34	C	1	0	1	5	1
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	17SEP2014 /105	14OCT2014 /-30	C	1	0	1	5	1
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	17SEP2014 /105	14OCT2014 /-30	C	1	0	1	5	1
	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	09JUL2014 /35	Unknown/NA	C	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0008/70 /F/W2/Y	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	09JUL2014 /35	Unknown/NA	C	6	0	1	5	1
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	09JUL2014 /35	30JUL2014 /-106	C	1	0	1	5	1
109-0009/57 /M/W2/N	Vascular disorders/ Hypertension/ HYPERTENSION	22JUL2014 /13	Unknown/NA	I	6	0	1	5	2
	Psychiatric disorders/ Insomnia/ INSOMNIA	30JUL2014 /21	11AUG2014 /-36	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0009/57 /M/W2/N	Injury, poisoning and procedural complications/ Fall/ FALL	19AUG2014 /41	19AUG2014 /-28	I	1	1	1	5	1
	Vascular disorders/ Hypertension/ HYPERTENSION	02SEP2014 /55	02SEP2014 /-14	I	1	0	1	5	3
	Skin and subcutaneous tissue disorders/ Dry skin/ DRY SKIN WHOLE BODY	30JUL2014 /21	Unknown/NA	C	6	0	1	5	1
109-0010/65 /M/W2/N	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT PAIN	21JUL2014 /12	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0011/64 /M/A4/N	Nervous system disorders/ Dizziness/ DIZZINESS	12OCT2014 /17	23OCT2014 /-41	I	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITIS (CHEST)	07JAN2015 /104	Unknown/NA	I	6	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	23OCT2014 /28	Unknown/NA	I	6	0	1	5	1
109-0013/64 /F/W2/N	Psychiatric disorders/ Mental status changes/ ALTERED MENTAL STATUS	23NOV2014 /18	Unknown/NA	C	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0013/64 /F/W2/N	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	21NOV2014 /16	23NOV2014 /-134	C	1	1	1	4 [CM]	3
	Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	15JAN2015 /71	Unknown/NA	I	6	0	1	5	1
	Gastrointestinal disorders/ Dyspepsia/ DYSPEPSIA	20MAR2015 /135	Unknown/NA	C	6	1	1	5	1
	Gastrointestinal disorders/ Pancreatitis/ PANCREATITIS	14MAR2015 /129	26MAR2015 /-11	C	1	1	3 /16MAR2015 /30MAR2015	4 [CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0013/64 /F/W2/N	Psychiatric disorders/ Anxiety/ ANXIETY	26MAR2015 /141	Unknown/NA	I	6	0	1	5	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL CRAMPING	06NOV2014 /1	Unknown/NA	I	6	0	1	5	1
	Hepatobiliary disorders/ Gallbladder pain/ GALLBLADDER PAIN	03APR2015 /149	Unknown/NA	I	6	0	1	5	2
	Psychiatric disorders/ Insomnia/ INSOMNIA	16MAR2015 /131	26MAR2015 /-11	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0013/64 /F/W2/N	Injury, poisoning and procedural complications/ Fall/ FALL	29MAR2015 /144	Unknown/NA	I	6	0	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ LOWER EXTREMITY EDEMA	16MAR2015 /131	Unknown/NA	C	6	1	1	5	2
110-0003/63 /M/OTH/N	General disorders and administration site conditions/ Oedema peripheral/ EDEMA, BILATERAL LOWER EXTREMITIES (LIMBS)	23JUL2012 /14	24SEP2012 /-77	C	1	1	1	5	1
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	30JUL2012 /21	27AUG2012 /-105	C	1	1	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
110-0003/63 /M/OTH/N	General disorders and administration site conditions/ Asthenia/ WEAKNESS	30SEP2012 /83	02OCT2012 /-69	C	1	1	3 /30SEP2012 /02OCT2012	5[CD]	3
	Nervous system disorders/ Somnolence/ DROWSINESS	14AUG2012 /36	18NOV2012 /-22	C	1	0	1	5	1
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	20AUG2012 /42	Unknown/NA	C	6	1	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	28JUL2012 /19	28JUL2012 /-135	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
110-0003/63 /M/OTH/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	09OCT2012 /92	Unknown/NA	C	2	0	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	28JUL2012 /19	28JUL2012 /-135	C	1	0	1	3	1
	Nervous system disorders/ Dizziness/ DIZZINESS	19JUL2012 /10	20JUL2012 /-143	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	16JUL2012 /7	23JUL2012 /-140	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
110-0003/63 /M/OTH/N	Skin and subcutaneous tissue disorders/ Blister/ BLISTERS, LOWER EXTREMITY	12NOV2012 /126	19NOV2012 /-21	C	1	1	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA, LEFT UPPER EXTREMITY, HAND	14AUG2012 /36	24SEP2012 /-77	C	1	0	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	22OCT2012 /105	26NOV2012 /-14	I	1	1	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	22OCT2012 /105	26NOV2012 /-14	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
110-0003/63 /M/OTH/N	Psychiatric disorders/ Agitation/ AGITATION	20AUG2012 /42	Unknown/NA	C	6	0	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA, LEFT LEG AND LEFT ARM	25SEP2012 /78	09OCT2012 /-62	C	1	3	1	5	2
	Skin and subcutaneous tissue disorders/ Night sweats/ NIGHT SWEATS	04SEP2012 /57	Unknown/NA	C	6	0	1	5	1
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Tumour pain/ PAIN IN MALIGNANT MASS, STERNUM (MUSCULOSKELTAL PAIN)	29OCT2012 /112	Unknown/NA	C	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
110-0003/63 /M/OTH/N	General disorders and administration site conditions/ Oedema peripheral/ EDEMA, LEFT LEG AND ARM	09OCT2012 /92	05NOV2012 /-35	C	1	1	1	5	1
	Skin and subcutaneous tissue disorders/ Hyperhidrosis/ SWEATING	06AUG2012 /28	Unknown/NA	C	6	0	1	5	1
	Infections and infestations/ Cellulitis/ CELLULITIS, BILATERAL LOWER EXTREMITIES	30SEP2012 /83	02OCT2012 /-69	C	1	1	3 /01OCT2012 /09OCT2012	5	1
	Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	10DEC2012 /154	11DEC2012 /1	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
110-0003/63 /M/OTH/N	Nervous system disorders/ Somnolence/ SOMNOLENCE	19NOV2012 /133	Unknown/NA	C	6	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Rales/ COARSE CRACKLES IN RIGHT LUNG	09OCT2012 /92	22NOV2012 /-18	C	1	0	1	5	1
	Gastrointestinal disorders/ Dyspepsia/ HEARTBURN	02OCT2012 /85	Unknown/NA	C	6	1	1	5	1
110-0004/53 /M/A4/N	Gastrointestinal disorders/ Flatulence/ FLATULENCE	01NOV2012 /7	11NOV2012 /-53	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
110-0004/53 /M/A4/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	20NOV2012 /26	29NOV2012 /-35	C	1	1	1	5	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	30NOV2012 /36	Unknown/NA	C	6	0	1	4	1
	Renal and urinary disorders/ Pollakiuria/ URINARY FREQUENCY	03JAN2013 /70	10JAN2013 /7	C	1	0	1	4	1
	Psychiatric disorders/ Confusional state/ CONFUSION	30OCT2012 /5	04NOV2012 /-60	I	3	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
110-0004/53 /M/A4/N	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS, ENTIRE BODY	27DEC2012 /63	03JAN2013 /0	C	1	1	1	3	1
	Nervous system disorders/ Hepatic encephalopathy/ WORSENING OF HEPATIC ENCEPHALOPATHY	04NOV2012 /10	07NOV2012 /-57	C	1	1	3 /04NOV2012 /20NOV2012	4[CD]	2
	General disorders and administration site conditions/ Injection site pruritus/ ITCHINESS AT INJECTION SITE	13DEC2012 /49	13DEC2012 /-21	C	1	0	1	1	1
110-0007/62 /M/A4/Y	Infections and infestations/ Chest wall abscess/ WOUND INFECTION (CHEST WALL ABSCESS)	29JUL2013 /73	21AUG2013 /-114	C	3	1	3 /02AUG2013 /09AUG2013	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
110-0007/62 /M/A4/Y	Respiratory, thoracic and mediastinal disorders/ Cough/ DRY COUGH	07JUN2013 /21	Unknown/NA	C	6	1	1	5	1
	Vascular disorders/ Peripheral coldness/ CHILLS (COLD SENSITIVITY TO FEET)	13SEP2013 /119	Unknown/NA	C	6	0	1	5	1
	Infections and infestations/ Chest wall abscess/ WOUND INFECTION (RECURRENT CHEST WALL ABSCESES)	28AUG2013 /103	Unknown/NA	C	6	1	1	5	2
	Infections and infestations/ Chest wall abscess/ RECURRENT CHEST WALL ABSCESS	18DEC2013 /215	23DEC2013 /10	C	3	1	1	5 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
110-0007/62 /M/A4/Y	Infections and infestations/ Chest wall abscess/ CHEST WALL ABSCESS	21AUG2013 /96	27AUG2013 /-108	C	1	1	3 /21AUG2013 /30AUG2013	5[PD]	3
	General disorders and administration site conditions/ Chills/ CHILLS	30AUG2013 /105	31AUG2013 /-104	C	1	0	1	4	1
	Injury, poisoning and procedural complications/ Contusion/ BRUISING, BILATERAL FOREARMS	02AUG2013 /77	Unknown/NA	C	6	0	1	5	1
	Infections and infestations/ Tooth infection/ TOOTH INFECTION WITH FEVER AND CHILLS AFTER TOOTH EXTRACTION	09NOV2013 /176	09NOV2013 /-34	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
110-0007/62 /M/A4/Y	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	20MAY2013 /3	22MAY2013 /-205	C	1	0	1	5	1
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	31MAY2013 /14	04JUN2013 /-192	C	1	1	1	5[CD]	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH WITH STAIRS	24MAY2013 /7	12JUL2013 /-154	C	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	17MAY2013 /0	12JUL2013 /-154	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
110-0007/62 /M/A4/Y	General disorders and administration site conditions/ Injection site reaction/ INJECTION SITE REACTION	20JUL2013 /64	20JUL2013 /-146	C	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	07JUN2013 /21	21JUN2013 /-175	C	1	1	1	5	1
	Hepatobiliary disorders/ Jaundice/ JAUNDICE	27DEC2013 /224	Unknown/NA	C	2	0	1	5	3
	Reproductive system and breast disorders/ Gynaecomastia/ GYNECOMASTIA	12JUL2013 /56	06SEP2013 /-98	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
110-0007/62 /M/A4/Y	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHINESS, BILATERAL EXTREMITIES	19JUL2013 /63	Unknown/NA	C	6	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ PAIN IN EXTREMITY (BILATERAL KNEES)	12JUL2013 /56	Unknown/NA	C	6	0	1	5	1
	General disorders and administration site conditions/ Injection site reaction/ INJECTION SITE REACTION	13SEP2013 /119	Unknown/NA	C	6	1	1	5	1
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASE	27DEC2013 /224	Unknown/NA	C	2	2	3 /20DEC2013 /Unknown	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
110-0007/62 /M/A4/Y	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ RIGHT LATERAL RIB PAIN	26JUL2013 /70	Unknown/NA	C	6	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNY NOSE (POST NASAL DRIP)	13SEP2013 /119	Unknown/NA	C	6	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	30AUG2013 /105	31AUG2013 /-104	C	1	0	1	4	1
	Metabolism and nutrition disorders/ Decreased appetite/ LOSS OF APPETITE	14JUN2013 /28	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
110-0008/63 /F/BL/N	Gastrointestinal disorders/ Vomiting/ WORSENING OF VOMITING	09JUL2013 /0	09JUL2013 /-27	C	1	1	1	2	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	08AUG2013 /30	08AUG2013 /3	C	1	1	1	5 [PD]	2
	General disorders and administration site conditions/ Injection site pain/ SORE ARM DUE TO INJECTION SITE REACTION	09JUL2013 /0	15JUL2013 /-21	C	1	0	1	1	1
	Psychiatric disorders/ Mental status changes/ ALTERED MENTAL STATUS	08AUG2013 /30	26AUG2013 /21	C	1	1	1	4 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
110-0008/63 /F/BL/N	Gastrointestinal disorders/ Abdominal pain/ WORSENING OF ABDOMINAL PAIN	14JUL2013 /5	Unknown/NA	C	6	1	1	3	2
	Infections and infestations/ Clostridium difficile colitis/ CLOSTRIDIUM DIFFICILE COLITIS	08AUG2013 /30	26AUG2013 /21	C	1	1	1	5	3
	Psychiatric disorders/ Restlessness/ RESTLESSNESS OF LEGS AND HANDS	05AUG2013 /27	Unknown/NA	C	6	0	1	3	1
110-0011/77 /M/A1/Y	General disorders and administration site conditions/ Oedema peripheral/ EDEMA, BILATERAL EXTREMITIES	11MAR2015 /48	Unknown/NA	C	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
110-0011/77 /M/A1/Y	Vascular disorders/ Hypertension/ HYPERTENSION	29JAN2015 /7	Unknown/NA	I	6	1	1	5	3
	Skin and subcutaneous tissue disorders/ Erythema/ WORSENING OF REDNESS ON FACE	26FEB2015 /35	Unknown/NA	C	2	0	1	5	2
	Skin and subcutaneous tissue disorders/ Rash generalised/ RASH, BODY	10FEB2015 /19	Unknown/NA	C	2	1	1	5	2
	Injury, poisoning and procedural complications/ Contusion/ EASY BRUISING	12FEB2015 /21	Unknown/NA	C	2	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0001/37 /M/A4/Y	Skin and subcutaneous tissue disorders/ Palmar-plantar erythrodysaesthesia syndrome/ PALMAR-PLANTAR ERYTHRODYSESITHESIA SYNDROME	13AUG2012 /32	Unknown/NA	C	6	0	1	5	1
	Skin and subcutaneous tissue disorders/ Alopecia/ ALOPECIA	23AUG2012 /42	24SEP2012 /60	C	1	0	1	5	1
	General disorders and administration site conditions/ Non-cardiac chest pain/ CHEST PAIN NON-CARDIAC	26JUL2012 /14	06AUG2012 /11	C	1	2	1	5	1
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	18JUL2012 /6	26JUL2012 /0	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0004/64 /M/W2/N	Investigations/ Lymphocyte count decreased/ DECREASED LYMPHOCYTES	27JUN2013 /35	11JUL2013 /14	I	1	0	1	4	3
	Nervous system disorders/ Lethargy/ LETHARGY	07JUL2013 /45	Unknown/NA	C	6	0	1	4	2
	Skin and subcutaneous tissue disorders/ Rash/ RASH, ANTERIOR CHEST	06JUN2013 /14	20JUN2013 /-7	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
	Psychiatric disorders/ Mental status changes/ ALTERED MENTAL STATUS	03JUL2013 /41	07JUL2013 /10	C	1	1	1	4[Risk For Tumor Related Seizures Given Known Skull Based Metastasis, specificall y The Deep Sphenoid Lesion. Seizure Do Not Represent Clinical Disease Progression In Setting Of Radiographi c Stability.]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0004/64 /M/W2/N	Eye disorders/ Vision blurred/ BLURRED VISION, OS	11JUL2013 /49	Unknown/NA	C	6	0	1	4	2
	Injury, poisoning and procedural complications/ Skin abrasion/ LEFT ARM ABRASION	10JUL2013 /48	Unknown/NA	C	6	0	1	4	1
	Musculoskeletal and connective tissue disorders/ Muscular weakness/ MUSCLE WEAKNESS, LOWER LIMBS	08JUL2013 /46	Unknown/NA	C	6	0	1	4	2
	Nervous system disorders/ Seizure/ SEIZURE	03JUL2013 /41	07JUL2013 /10	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0004/64 /M/W2/N	Injury, poisoning and procedural complications/ Skin abrasion/ ABRASION RIGHT KNEE	18JUN2013 /26	11JUL2013 /14	C	1	0	1	4	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	08JUL2013 /46	Unknown/NA	C	6	0	1	4	3
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	20JUN2013 /28	27JUN2013 /0	C	1	1	1	3	1
	Blood and lymphatic system disorders/ Leukocytosis/ LEUCOCYTOSIS	11JUL2013 /49	31JUL2013 /34	C	1	0	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0004/64 /M/W2/N	Injury, poisoning and procedural complications/ Skin abrasion/ ABRASION, RIGHT HAND	23MAY2013 /0	30MAY2013 /-28	C	1	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	26MAY2013 /3	08JUL2013 /11	I	1	0	1	4	2
	Nervous system disorders/ Memory impairment/ MEMORY IMPAIRMENT	01JUN2013 /9	Unknown/NA	C	6	0	1	4	2
	Eye disorders/ Eye pain/ LEFT EYE PAIN	11JUL2013 /49	Unknown/NA	I	6	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0006/59 /M/W2/N	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	23APR2014 /195	Unknown/NA	C	6	2	1	4	3
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION ( RECURRENT)	23APR2014 /195	Unknown/NA	C	6	2	1	4	3
	Infections and infestations/ Fungal skin infection/ INFECTION, FUNGAL TO CHIN, THIGHS, BACK	19JAN2014 /101	Unknown/NA	I	6	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Pneumothorax/ PNEUMOTHORAX (RIGHT)	05MAY2014 /207	Unknown/NA	C	6	2	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0006/59 /M/W2/N	Nervous system disorders/ Diabetic neuropathy/ NEUROPATHY (DIABETIC)	02NOV2013 /23	13NOV2013 /-140	I	1	0	1	4	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	18APR2014 /190	Unknown/NA	I	6	0	1	4	3
	Skin and subcutaneous tissue disorders/ Erythema/ ERYTHEMA, RIGHT FOOT	13NOV2013 /34	27NOV2013 /-126	I	1	0	1	5	1
	Infections and infestations/ Influenza/ INFLUENZA	15NOV2013 /36	01DEC2013 /-122	C	1	3	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0006/59 /M/W2/N	Cardiac disorders/ Cardiac flutter/ FLUTTERING SENSATION, RIGHT CHEST WALL	13OCT2013 /3	13NOV2013 /-140	I	1	0	1	4	1
	Metabolism and nutrition disorders/ Hypomagnesaemia/ HYPOMAGNESEMIA	29JAN2014 /111	Unknown/NA	I	6	1	1	3	1
	Renal and urinary disorders/ Renal injury/ ACUTE RENAL INJURY	28APR2014 /200	Unknown/NA	C	6	2	1	4	3
	General disorders and administration site conditions/ Fatigue/ WORSENING FATIGUE	19OCT2013 /9	Unknown/NA	C	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0006/59 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Hepatic hydrothorax/ HEPATIC HYDROTHORAX	05MAY2014 /207	09MAY2014 /37	C	1	2	1	5	3
	Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION (LOWER)	08APR2014 /180	24APR2014 /22	C	1	3	1	4	2
	Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIA	30OCT2013 /20	Unknown/NA	I	6	1	1	4	3
	Skin and subcutaneous tissue disorders/ Ecchymosis/ PATCHY ECCHYMOSIS, CHIN	12MAR2014 /153	19MAR2014 /-14	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0006/59 /M/W2/N	Gastrointestinal disorders/ Gastrointestinal haemorrhage/ GI BLEEDING (ESOPHAGEAL VARICES HEMORRHAGE)	23APR2014 /195	12MAY2014 /40	I	4	3	3 /09APR2014 /Unknown	4 [CD]	5
	Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	09MAY2014 /211	Unknown/NA	C	6	2	1	5	1
	Skin and subcutaneous tissue disorders/ Rash/ RASH RIGHT ANTEROMEDIAL FOREARM	11OCT2013 /1	30OCT2013 /-154	C	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA (JOINT PAIN)	19OCT2013 /9	Unknown/NA	I	6	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0006/59 /M/W2/N	Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHE	19OCT2013 /9	Unknown/NA	I	6	0	1	3	2
111-0007/55 /M/W2/N	Nervous system disorders/ Burning sensation/ BURNING SENSATION, LEFT LOWER RIB CAGE	27MAR2014 /49	30JUN2014 /81	I	1	0	1	4	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	21FEB2014 /15	03JUL2014 /84	I	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ PAIN, RIGHT ANTERIOR RIB CAGE	13MAR2014 /35	30JUN2014 /81	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0006/58 /M/W2/N	Skin and subcutaneous tissue disorders/ Rash/ RASH	03MAY2013 /38	Unknown/NA	C	6	0	1	3	1
	Investigations/ Blood albumin decreased/ ALBUMIN LOW	15APR2013 /20	29APR2013 /-35	I	1	0	1	4[CD]	1
	Investigations/ Aspartate aminotransferase increased/ AST ELEVATION	01APR2013 /6	13MAY2013 /-21	I	1	0	1	3	2
	General disorders and administration site conditions/ Hernia pain/ ABDOMINAL PAIN (UMBILICAL HERNIA)	25APR2013 /30	26APR2013 /-38	I	1	0	1	5[Abdominal Pain Due To Umbilical Hernia]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0006/58 /M/W2/N	Musculoskeletal and connective tissue disorders/ Joint swelling/ JOINT SWELLING	29APR2013 /34	01MAY2013 /-33	C	1	1	3 /29APR2013 /06MAY2013	3	2
	Gastrointestinal disorders/ Abdominal pain upper/ UPPER ABDOMINAL (MIDLINE) PAIN	31MAR2013 /5	08APR2013 /-56	I	1	0	1	4 [PD]	2
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea exertional/ DYSPNEA ON EXERTION	06MAY2013 /41	Unknown/NA	C	6	0	1	4 [CD]	1
	Investigations/ Blood alkaline phosphatase increased/ ALK PHOS ELEVATION	01APR2013 /6	29APR2013 /-35	I	1	0	1	4 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0006/58 /M/W2/N	Gastrointestinal disorders/ Abdominal pain lower/ LOWER ABDOMINAL PAIN	13MAY2013 /48	14MAY2013 /-20	I	1	0	1	4 [CD]	1
	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LOWER EXTERMIT Y EDEMA	06MAY2013 /41	Unknown/NA	C	6	0	1	4 [CD]	1
	Investigations/ Platelet count decreased/ PLATELETS LOW	15APR2013 /20	29APR2013 /-35	I	1	0	1	4 [CD]	1
	Investigations/ Alanine aminotransferase increased/ ALT ELEVATION	01APR2013 /6	29APR2013 /-35	C	1	1	3 /01APR2013 /06MAY2013	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0006/58 /M/W2/N	Investigations/ Blood albumin decreased/ ALBUMIN LOW	01APR2013 /6	15APR2013 /-49	I	1	0	1	4 [CD]	2
	Investigations/ Haemoglobin decreased/ HEMOGLOBIN LOW	01APR2013 /6	Unknown/NA	C	6	0	1	4 [CD]	1
	Investigations/ Lymphocyte count decreased/ LYMPHOCYTE LOW	13MAY2013 /48	28JUN2013 /25	I	1	0	1	4 [CD]	1
	Investigations/ Aspartate aminotransferase increased/ AST ELEVATION	13MAY2013 /48	28JUN2013 /25	I	1	0	1	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0006/58 /M/W2/N	Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN	29APR2013 /34	01MAY2013 /-33	I	1	1	3 /29APR2013 /06MAY2013	3	3
	Investigations/ Blood albumin decreased/ ALBUMIN LOW	29APR2013 /34	Unknown/NA	C	6	0	1	4 [CD]	2
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ BILATERAL ARM TENDERNESS	06MAY2013 /41	09MAY2013 /-25	I	1	0	1	4 [CD]	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	27MAR2013 /1	Unknown/NA	C	6	0	1	4 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0006/58 /M/W2/N	Investigations/ Alanine aminotransferase increased/ ALT ELEVATION	29APR2013 /34	13MAY2013 /-21	I	1	0	1	3	2
	Investigations/ Alanine aminotransferase increased/ ALT ELEVATION	13MAY2013 /48	Unknown/NA	C	6	0	1	3	3
	Investigations/ Aspartate aminotransferase increased/ AST ELEVATION	28JUN2013 /94	Unknown/NA	C	6	0	1	3	2
	Investigations/ Lymphocyte count decreased/ LYMPHOCYTE LOW	01APR2013 /6	30APR2013 /-34	I	1	0	1	4 [CD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0009/50 /M/A8/N	Investigations/ Haemoglobin decreased/ HEMOGLOBIN LOW	24JUL2013 /35	Unknown/NA	C	6	0	1	4 [CD]	1
	Investigations/ Alanine aminotransferase increased/ ALT ELEVATION	26JUN2013 /7	21AUG2013 /7	C	1	0	1	3	1
	Investigations/ White blood cell count decreased/ WBC LOW	24JUL2013 /35	07AUG2013 /-7	I	1	0	1	4 [CD]	2
	Investigations/ Platelet count decreased/ PLATELETS LOW	24JUL2013 /35	07AUG2013 /-7	C	1	0	1	4 [CD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0009/50 /M/A8/N	Nervous system disorders/ Somnolence/ DROWSINESS	04SEP2013 /77	Unknown/NA	C	6	0	1	5 [PD]	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL BLOATING	13SEP2013 /86	Unknown/NA	C	6	0	1	5 [PD]	1
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITIS	31JUL2013 /42	Unknown/NA	C	6	1	1	4 [CD]	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	03JUL2013 /14	24JUL2013 /-21	I	1	0	1	4 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0009/50 /M/A8/N	Investigations/ Aspartate aminotransferase increased/ AST ELEVATION	07AUG2013 /49	21AUG2013 /7	C	1	0	1	3	2
	Investigations/ Platelet count decreased/ PLATELETS LOW	04SEP2013 /77	Unknown/NA	C	6	0	1	4 [CD]	1
	Investigations/ Blood sodium decreased/ SODIUM LOW	26JUN2013 /7	24JUL2013 /-21	I	1	0	1	4 [Hyperglyc emia]	1
	Gastrointestinal disorders/ Abdominal discomfort/ ABDOMINAL DISCOMFORT	26JUN2013 /7	03JUL2013 /-42	I	1	0	1	4 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0009/50 /M/A8/N	Investigations/ Blood albumin decreased/ ALBUMIN LOW	24JUL2013 /35	07AUG2013 /-7	C	1	0	1	4 [CD]	2
	Investigations/ Blood albumin decreased/ ALBUMIN LOW	26JUN2013 /7	24JUL2013 /-21	I	1	0	1	4 [CD]	1
	Investigations/ Aspartate aminotransferase increased/ AST ELEVATION	21AUG2013 /63	Unknown/NA	C	6	0	1	3	3
	Investigations/ Lymphocyte count decreased/ LYMPHOCYTES LOW	26JUN2013 /7	Unknown/NA	C	6	0	1	4 [CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0009/50 /M/A8/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	03JUL2013 /14	17JUL2013 /-28	C	1	0	1	4[CD]	2
	Investigations/ Aspartate aminotransferase increased/ AST ELEVATION	26JUN2013 /7	07AUG2013 /-7	C	1	0	1	3	1
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	08JUL2013 /19	10JUL2013 /-35	I	1	1	3 /09JUL2013 /17JUL2013	4[Underlyin g Disease]	3
	Investigations/ Blood albumin decreased/ ALBUMIN LOW	07AUG2013 /49	21AUG2013 /7	C	1	0	1	4[CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0009/50 /M/A8/N	Investigations/ Platelet count decreased/ PLATELETS LOW	21AUG2013 /63	04SEP2013 /21	C	1	0	1	4 [CD]	2
	Investigations/ Blood glucose increased/ GLUCOSE ELEVATION	26JUN2013 /7	Unknown/NA	C	6	0	1	5 [Subject Is A Diabetic And At Times Did Not Take All Diabetic Medicines And Prescribed]	3
	Investigations/ Platelet count decreased/ PLATELETS LOW	26JUN2013 /7	24JUL2013 /-21	I	1	0	1	4 [CD]	1
	Investigations/ Alanine aminotransferase increased/ ALT ELEVATION	21AUG2013 /63	Unknown/NA	C	6	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0009/50 /M/A8/N	Investigations/ Blood bilirubin increased/ TOTAL BILIRUBIN ELEVATION	07AUG2013 /49	Unknown/NA	C	6	0	1	4[CD]	2
	Investigations/ Platelet count decreased/ PLATELETS LOW	07AUG2013 /49	21AUG2013 /7	C	1	0	1	4[CD]	1
	Investigations/ Blood alkaline phosphatase increased/ ALK PHOS ELEVATION	26JUN2013 /7	24JUL2013 /-21	I	1	0	1	4[CD]	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	03JUL2013 /14	09JUL2013 /-36	I	1	0	1	4[Disorder Of Bowel Function]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0009/50 /M/A8/N	Investigations/ Blood bilirubin increased/ TOTAL BILIRUBIN ELEVATION	26JUN2013 /7	07AUG2013 /-7	I	1	0	1	4 [CD]	1
112-0011/56 /M/A4/Y	Investigations/ Blood alkaline phosphatase increased/ ALK PHOS (HIGH)	28MAR2014 /77	Unknown/NA	C	6	0	1	4 [CD]	3
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	26JAN2014 /16	26JAN2014 /-26	C	1	1	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	18JAN2014 /8	14FEB2014 /-7	C	1	1	1	5 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0011/56 /M/A4/Y	Investigations/ Alanine aminotransferase increased/ ALT (HIGH)	18JAN2014 /8	28MAR2014 /35	C	1	0	1	3	1
	Investigations/ Blood alkaline phosphatase increased/ ALK PHOS (HIGH)	18JAN2014 /8	14FEB2014 /-7	C	1	0	1	3	1
	Gastrointestinal disorders/ Dyspepsia/ INDIGESTION	19JAN2014 /9	22JAN2014 /-30	C	1	1	1	4 [CD]	1
	Gastrointestinal disorders/ Abdominal pain upper/ MILD RUQ TENDERNESS	28FEB2014 /49	Unknown/NA	C	6	0	1	5 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0011/56 /M/A4/Y	Investigations/ Blood glucose increased/ GLUCOSE (HIGH)	18JAN2014 /8	Unknown/NA	C	6	0	1	4 [CM]	1
	Investigations/ Aspartate aminotransferase increased/ AST (HIGH)	18JAN2014 /8	28FEB2014 /7	C	1	0	1	3	1
	General disorders and administration site conditions/ Mucosal dryness/ DRY MUCOSA	31JAN2014 /21	Unknown/NA	C	6	0	1	5 [CD]	1
	General disorders and administration site conditions/ Pain/ BODY ACHES	18JAN2014 /8	20JAN2014 /-32	C	1	1	1	5 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0011/56 /M/A4/Y	Investigations/ Lymphocyte count decreased/ LYMPHOCYTE (LOW)	18JAN2014 /8	28FEB2014 /7	C	1	0	1	3	2
	Investigations/ Alanine aminotransferase increased/ ALT (HIGH)	28MAR2014 /77	Unknown/NA	C	6	0	1	4 [CD]	2
	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ LEFT RIB PAIN	29JAN2014 /19	14FEB2014 /-7	C	1	0	1	5 [CD]	1
	Cardiac disorders/ Tachycardia/ MILD TACHYCARDIC	28FEB2014 /49	07MAR2014 /14	C	1	0	1	5 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0011/56 /M/A4/Y	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	19JAN2014 /9	14FEB2014 /-7	C	1	0	1	4 [CD]	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	31JAN2014 /21	14FEB2014 /-7	I	1	1	1	3	1
	General disorders and administration site conditions/ Injection site erythema/ MILD ERYTHEMA AT INJECTION SITE	28FEB2014 /49	28MAR2014 /35	C	1	0	1	1	1
112-0012/71 /M/W2/N	Investigations/ Blood glucose increased/ GLUCOSE (ELEVATED)	30MAY2014 /7	13JUN2014 /-56	C	2	0	1	4 [CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0012/71 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea exertional/ DYSPNEA ON EXERTION	13JUN2014 /21	Unknown/NA	I	6	0	1	4 [CD]	2
	Musculoskeletal and connective tissue disorders/ Muscle spasms/ LEG CRAMPING	27JUN2014 /35	Unknown/NA	I	6	0	1	3	1
	General disorders and administration site conditions/ Pain/ GENERALIZED BODY ACHES	01AUG2014 /70	Unknown/NA	I	6	0	1	4 [CD]	1
	Investigations/ Blood glucose increased/ GLUCOSE (ELEVATED)	08AUG2014 /77	Unknown/NA	C	6	0	1	4 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0012/71 /M/W2/N	Investigations/ Activatedpartial thromboplastin time prolonged/ APTT (ELEVATED)	08AUG2014 /77	Unknown/NA	C	6	0	1	5 [CD]	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	26JUN2014 /34	Unknown/NA	I	6	0	1	3	1
	Gastrointestinal disorders/ Abdominal pain upper/ RUQ PAIN	03JUN2014 /11	Unknown/NA	I	6	1	1	4 [CD]	1
	Eye disorders/ Cystoid macular oedema/ MILD CYSTOID INTRARETINAL FLUID IN RIGHT EYE	31JUL2014 /69	Unknown/NA	C	6	1	1	5 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0012/71 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL EDEMA (LOWER AND UPPER EXTREMITIES)	23JUN2014 /31	Unknown/NA	C	6	0	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	30MAY2014 /7	30MAY2014 /-70	I	1	0	1	3	1
	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LOWER EXTERMITY EDEMA	30MAY2014 /7	06JUN2014 /-63	C	1	0	1	5[CD]	3
	Musculoskeletal and connective tissue disorders/ Back pain/ RIGHT MID-BACK PAIN	03JUN2014 /11	Unknown/NA	I	6	1	1	4[CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0012/71 /M/W2/N	Investigations/ Lymphocyte count decreased/ LYMPHOCYTE (LOW)	30MAY2014 /7	Unknown/NA	C	6	0	1	2	3
	Gastrointestinal disorders/ Vomiting/ VOMITING	26JUN2014 /34	26JUN2014 /-43	I	1	0	1	3	1
	Investigations/ Activatedpartialthromboplastin time prolonged/ APTT (ELEVATED)	13JUN2014 /21	11JUL2014 /-28	C	1	0	1	4[CD]	2
	Investigations/ Lymphocyte count decreased/ LYMPHOCYTE (LOW)	25JUL2014 /63	Unknown/NA	C	6	0	1	2	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0012/71 /M/W2/N	Investigations/ Blood albumin decreased/ ALBUMIN (LOW)	11JUL2014 /49	Unknown/NA	C	6	0	1	4 [CD]	2
	Investigations/ Activatedpartial thromboplastin time prolonged/ APTT (ELEVATED)	11JUL2014 /49	08AUG2014 /0	C	1	0	1	5 [CD]	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA (DECREASED APPETITE)	25JUL2014 /63	01AUG2014 /-7	C	1	0	1	3	1
	Investigations/ International normalised ratio increased/ INR (ELEVATED)	27JUN2014 /35	Unknown/NA	I	6	0	1	5 [CM]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0012/71 /M/W2/N	Investigations/ Lymphocyte count decreased/ LYMPHOCYTE (LOW)	11JUL2014 /49	25JUL2014 /-14	C	1	0	1	2	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	24MAY2014 /1	24MAY2014 /-76	I	1	0	1	3	1
	Investigations/ Haemoglobin decreased/ HEMOGLOBIN (LOW)	27JUN2014 /35	Unknown/NA	C	6	0	1	4[CD]	2
	Investigations/ Blood albumin decreased/ ALBUMIN (LOW)	27JUN2014 /35	11JUL2014 /-28	C	1	0	1	4[CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0012/71 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	13JUN2014 /21	Unknown/NA	C	6	0	1	3	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	24MAY2014 /1	24MAY2014 /-76	I	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT KNEE PAIN	26MAY2014 /3	Unknown/NA	I	6	0	1	5 [CD]	1
	Investigations/ Blood glucose increased/ GLUCOSE (ELEVATED)	13JUN2014 /21	08AUG2014 /0	C	1	0	1	4 [CD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0012/71 /M/W2/N	Investigations/ Aspartate aminotransferase increased/ AST (ELEVATED)	13JUN2014 /21	11JUL2014 /-28	C	1	0	1	3	1
	Investigations/ International normalised ratio increased/ INR (ELEVATED)	13JUN2014 /21	27JUN2014 /-42	C	1	0	1	5 [CM]	3
112-0013/28 /F/W2/N	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL UPPER EXTREMITY EDEMA	19JUN2014 /27	27JUN2014 /-14	C	1	0	1	5 [CD]	1
	Investigations/ Blood glucose increased/ GLUCOSE (ELEVATED)	27JUN2014 /35	11JUL2014 /0	C	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0013/28 /F/W2/N	Investigations/ Blood cholesterol increased/ CHOLESTEROL (ELEVATED)	30MAY2014 /7	13JUN2014 /-28	C	1	0	1	3	1
	Investigations/ Blood cholesterol increased/ CHOLESTEROL (ELEVATED)	27JUN2014 /35	Unknown/NA	C	6	0	1	3	1
	Skin and subcutaneous tissue disorders/ Erythema/ BILATERAL ERYTHEMA (HANDS AND FOREARMS)	30JUN2014 /38	Unknown/NA	C	6	0	1	5[CD]	2
	Investigations/ Blood alkaline phosphatase increased/ ALK PHOS (ELEVATED)	11JUL2014 /49	29AUG2014 /49	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0013/28 /F/W2/N	Investigations/ Alanine aminotransferase increased/ ALT (ELEVATED)	11JUL2014 /49	29AUG2014 /49	C	1	0	1	3	2
	Investigations/ Aspartate aminotransferase increased/ AST (ELEVATED)	11JUL2014 /49	29AUG2014 /49	C	1	0	1	3	1
	Investigations/ Blood glucose increased/ GLUCOSE (ELEVATED)	11JUL2014 /49	29AUG2014 /49	C	1	0	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ PROGRESSIVE COUGH	09JUL2014 /47	10JUL2014 /-1	I	1	3	1	4 [Disease]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0013/28 /F/W2/N	Psychiatric disorders/ Sleep disorder/ SLEEP DISTURBANCE	11JUL2014 /49	Unknown/NA	I	6	0	1	5 [PD]	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	20JUN2014 /28	27JUN2014 /-14	C	1	0	1	4 [CD]	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	27JUN2014 /35	Unknown/NA	C	6	0	1	3	1
	Investigations/ Blood glucose increased/ GLUCOSE (ELEVATED)	29AUG2014 /98	Unknown/NA	C	6	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0013/28 /F/W2/N	Investigations/ Lymphocyte count decreased/ LYMPHOCYTES (LOW)	29AUG2014 /98	Unknown/NA	C	6	0	1	2	3
	Investigations/ Blood alkaline phosphatase increased/ ALK PHOS (ELEVATED)	30MAY2014 /7	27JUN2014 /-14	C	1	0	1	4 [CD]	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	19JUN2014 /27	Unknown/NA	I	6	0	1	3	1
	Gastrointestinal disorders/ Nausea/ INTERMITTENT NAUSEA	19JUN2014 /27	Unknown/NA	I	6	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0013/28 /F/W2/N	Investigations/ Blood glucose increased/ GLUCOSE (ELEVATED)	13JUN2014 /21	27JUN2014 /-14	C	1	0	1	3	1
	Investigations/ White blood cell count decreased/ WBC (LOW)	13JUN2014 /21	27JUN2014 /-14	C	1	0	1	3	1
	Investigations/ Lymphocyte count decreased/ LYMPHOCYTES (LOW)	30MAY2014 /7	27JUN2014 /-14	C	1	0	1	2	2
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	09JUL2014 /47	10JUL2014 /-1	I	1	0	1	4[CD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0013/28 /F/W2/N	Gastrointestinal disorders/ Vomiting/ INTRACTABLE VOMITING	15JUN2014 /23	19JUN2014 /-22	I	1	1	1	5 [CD]	3
	General disorders and administration site conditions/ Pain/ BODY ACHES	10JUN2014 /18	19JUN2014 /-22	C	1	1	1	4 [CD]	1
	Gastrointestinal disorders/ Nausea/ 1. INTRACTABLE NAUSEA	15JUN2014 /23	19JUN2014 /-22	I	1	3	1	4 [CD]	3
	Gastrointestinal disorders/ Nausea/ PERSISTENT NAUSEA	10JUN2014 /18	27JUN2014 /-14	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0013/28 /F/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	23MAY2014 /0	30MAY2014 /-42	C	1	0	1	5[CM]	2
	Investigations/ International normalised ratio increased/ INR (ELEVATED)	27JUN2014 /35	11JUL2014 /0	C	1	0	1	5[LabError]	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	10JUN2014 /18	15JUN2014 /-26	I	1	0	1	3	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	13JUN2014 /21	Unknown/NA	C	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0013/28 /F/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	30MAY2014 /7	20JUN2014 /-21	C	1	0	1	4 [CM]	3
	General disorders and administration site conditions/ Non-cardiac chest pain/ CHEST PAIN (NON-CARDIAC)	15JUL2014 /53	02AUG2014 /22	C	1	3	1	4 [Disease]	3
112-0014/79 /M/A8/Y	Investigations/ Aspartate aminotransferase increased/ AST (ELEVATED)	11JUL2014 /35	Unknown/NA	C	6	0	1	3	1
	Investigations/ Blood cholesterol increased/ CHOLESTEROL (ELEVATED)	11JUL2014 /35	25JUL2014 /-21	C	1	0	1	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0014/79 /M/A8/Y	Metabolism and nutrition disorders/ Decreased appetite/ DECREASE APPETITE	27JUN2014 /21	Unknown/NA	C	6	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	19SEP2014 /105	Unknown/NA	C	6	1	1	5 [PD]	2
	Investigations/ Weight decreased/ WEIGHT LOSS	25JUL2014 /49	01AUG2014 /-14	C	1	0	1	4 [PD]	1
	Investigations/ Weight decreased/ WEIGHT LOSS	01AUG2014 /56	Unknown/NA	C	6	0	1	4 [PD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0014/79 /M/A8/Y	Investigations/ Blood cholesterol increased/ CHOLESTEROL (ELEVATED)	25JUL2014 /49	Unknown/NA	C	6	0	1	3	4
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	11JUL2014 /35	Unknown/NA	C	6	0	1	4 [CD]	1
	Investigations/ Blood cholesterol increased/ CHOLESTEROL (ELEVATED)	13JUN2014 /7	11JUL2014 /-35	C	1	0	1	3	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	27JUN2014 /21	Unknown/NA	C	6	0	1	4 [CD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0014/79 /M/A8/Y	Investigations/ Blood glucose increased/ GLUCOSE (ELEVATED)	27JUN2014 /21	11JUL2014 /-35	C	1	0	1	4 [CD]	1
	Investigations/ Blood potassium decreased/ POTASSIUM (LOW)	27JUN2014 /21	Unknown/NA	C	6	0	1	4 [CD]	1
	Investigations/ Blood glucose increased/ GLUCOSE (ELEVATED)	25JUL2014 /49	Unknown/NA	C	6	0	1	3	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	11JUL2014 /35	18JUL2014 /-28	I	1	0	1	4 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0014/79 /M/A8/Y	Investigations/ Blood glucose increased/ GLUCOSE (ELEVATED)	11JUL2014 /35	25JUL2014 /-21	C	1	0	1	3	2
	Investigations/ White blood cell count decreased/ WBC (LOW)	13JUN2014 /7	25JUL2014 /-21	C	1	0	1	3	2
	Investigations/ Blood glucose increased/ GLUCOSE (ELEVATED)	13JUN2014 /7	27JUN2014 /-49	C	1	0	1	3	2
	Investigations/ White blood cell count decreased/ WBC (LOW)	25JUL2014 /49	Unknown/NA	C	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0014/79 /M/A8/Y	General disorders and administration site conditions/ Gait disturbance/ GAIT DISTURBANCE	11JUL2014 /35	18JUL2014 /-28	C	1	0	1	4 [CD]	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	11JUL2014 /35	18JUL2014 /-28	C	1	0	1	3	1
112-0015/66 /M/A8/N	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT NEOPLASM PROGRESSION	02JAN2015 /70	02JAN2015 /30	C	4	0	1	5 [PD]	5
	Respiratory, thoracic and mediastinal disorders/ Pleuritic pain/ PLEURITIC CHEST PAIN	26NOV2014 /33	12DEC2014 /9	C	1	0	1	4 [PD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0015/66 /M/A8/N	Investigations/ Blood bilirubin increased/ ELEVATED TOTAL BILIRUBIN	31OCT2014 /7	26NOV2014 /-7	C	1	0	1	4 [CD]	1
	Investigations/ Blood glucose increased/ ELEVATED GLUCOSE	31OCT2014 /7	Unknown/NA	C	6	0	1	4 [CD]	1
	Investigations/ Blood bilirubin increased/ ELEVATED TOTAL BILIRUBIN	26NOV2014 /33	Unknown/NA	C	6	0	1	4 [CD]	2
	Respiratory, thoracic and mediastinal disorders/ Pleuritic pain/ PLEURITIC CHEST PAIN	12DEC2014 /49	Unknown/NA	C	6	0	1	4 [PD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0015/66 /M/A8/N	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITIS	23NOV2014 /30	03DEC2014 /0	C	1	0	1	4 [CD]	1
	Skin and subcutaneous tissue disorders/ Rash/ RASH	23NOV2014 /30	03DEC2014 /0	C	1	0	1	4 [CD]	1
	Respiratory, thoracic and mediastinal disorders/ Pleuritic pain/ PLEURITIC CHEST PAIN	09NOV2014 /16	26NOV2014 /-7	I	1	0	1	5 [PD]	2
	Investigations/ Blood uric acid increased/ ELEVATED URIC ACID	03DEC2014 /40	Unknown/NA	C	6	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0001/61 /M/W2/N	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHINESS OF LEFT UPPER ARM	17DEC2012 /115	18DEC2012 /-41	C	1	1	1	3	1
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING UPPER RIGHT ARM	03DEC2012 /101	03DEC2012 /-56	I	1	0	1	3	1
	Nervous system disorders/ Dysgeusia/ METALLIC TASTE	03DEC2012 /101	03DEC2012 /-56	C	1	0	1	2	1
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHINESS OF RIGHT UPPER ARM	07JAN2013 /136	08JAN2013 /-20	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0001/61 /M/W2/N	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHINESS OF LEFT UPPER ARM	03JAN2013 /132	04JAN2013 /-24	C	1	0	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ NASAL MUCOUS	02OCT2012 /39	02OCT2012 /-118	C	1	0	1	3	1
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHINESS ON FACE - BOTH CHEECKS AND BOTH UPPER ARMS	11NOV2012 /79	14NOV2012 /-75	I	1	1	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Epistaxis/ EPISTAXIS	27OCT2012 /64	28OCT2012 /-92	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0001/61 /M/W2/N	Nervous system disorders/ Dizziness/ LIGHTHEADEDNESS	19NOV2012 /87	19NOV2012 /-70	C	1	0	1	3	1
	Nervous system disorders/ Dysgeusia/ METALLIC TASTE	19NOV2012 /87	19NOV2012 /-70	C	1	0	1	2	1
	Nervous system disorders/ Dysgeusia/ METALLIC TASTE	17SEP2012 /24	17SEP2012 /-133	C	1	0	1	3	1
	Skin and subcutaneous tissue disorders/ Rash/ RASH LEFT SIDE OF CHEST	12NOV2012 /80	13NOV2012 /-76	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0001/61 /M/W2/N	General disorders and administration site conditions/ Fatigue/ TIREDNESS	08JAN2013 /137	24JAN2013 /-4	I	1	0	1	3	2
	General disorders and administration site conditions/ Asthenia/ WEAKNESS	02OCT2012 /39	08JAN2013 /-20	C	1	0	1	3	1
	Nervous system disorders/ Dysgeusia/ METALLIC TASTE	24SEP2012 /31	24SEP2012 /-126	C	1	0	1	3	1
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING BOTH ARMS	15NOV2012 /83	17NOV2012 /-72	I	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0001/61 /M/W2/N	Nervous system disorders/ Dysgeusia/ METALLIC TASTE	14JAN2013 /143	14JAN2013 /-14	C	1	0	1	2	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	13DEC2012 /111	10JAN2013 /-18	I	1	1	1	3	1
	Gastrointestinal disorders/ Lip pain/ RIGHT UPPER LIP SORENESS	15NOV2012 /83	23NOV2012 /-66	C	1	0	1	4	1
	Nervous system disorders/ Dysgeusia/ METALLIC TASTE	17DEC2012 /115	18DEC2012 /-41	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0001/61 /M/W2/N	Nervous system disorders/ Dysgeusia/ METALLIC TASTE	23JAN2013 /152	23JAN2013 /-5	C	1	0	1	3	1
	Nervous system disorders/ Headache/ HEADACHE	07OCT2012 /44	07OCT2012 /-113	C	1	0	1	3	1
	Nervous system disorders/ Dysgeusia/ METALLIC TASTE	01OCT2012 /38	01OCT2012 /-119	C	1	0	1	3	1
	Gastrointestinal disorders/ Stomatitis/ 2 SORES IN MOUTH ON RIGHT SIDE	14DEC2012 /112	17DEC2012 /-42	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0001/61 /M/W2/N	General disorders and administration site conditions/ Injection site pruritus/ ITCHING, RIGHT UPPER ARM, POST INJECTION	23JAN2013 /152	23JAN2013 /-5	C	1	0	1	3	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	13DEC2012 /111	14DEC2012 /-45	C	1	0	1	3	1
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHINESS UPPER LEFT ARM	14JAN2013 /143	14JAN2013 /-14	C	1	1	1	3	1
	Investigations/ Blood creatinine increased/ INCREASE IN CREATININE LEVEL	01SEP2012 /8	Unknown/NA	C	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0001/61 /M/W2/N	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHINESS UPPER LEFT ARM	10DEC2012 /108	10DEC2012 /-49	I	1	1	1	3	1
	Infections and infestations/ Subcutaneous abscess/ SMALL ABSCESS LEFT BUTTOCK	29OCT2012 /66	03NOV2012 /-86	C	1	0	1	4	1
	Nervous system disorders/ Dysgeusia/ METALLIC TASTE	26NOV2012 /94	26NOV2012 /-63	C	1	0	1	2	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	19NOV2012 /87	19NOV2012 /-70	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0001/61 /M/W2/N	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHINESS ON CHEST	17DEC2012 /115	18DEC2012 /-41	C	1	0	1	3	1
	Nervous system disorders/ Dysgeusia/ METALLIC TASTE	22OCT2012 /59	22OCT2012 /-98	C	1	0	1	2	1
	Nervous system disorders/ Dysgeusia/ METALLIC TASTE	08OCT2012 /45	08OCT2012 /-112	C	1	0	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ NASAL DISCHARGE	14DEC2012 /112	20DEC2012 /-39	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0001/61 /M/W2/N	Skin and subcutaneous tissue disorders/ Erythema/ REDNESS RIGHT SIDE OF BUTTOCKS	13NOV2012 /81	20NOV2012 /-69	C	1	0	1	4	1
	Nervous system disorders/ Dysgeusia/ METALLIC TASTE	03JAN2013 /132	03JAN2013 /-25	C	1	0	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	10SEP2012 /17	11SEP2012 /-139	I	1	0	1	3	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	10SEP2012 /17	01JAN2013 /-27	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0001/61 /M/W2/N	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHINESS ON RIGHT UPPER ARM	17DEC2012 /115	17DEC2012 /-42	C	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Muscle spasms/ BILATERAL LEG CRAMPS	11SEP2012 /18	21SEP2012 /-129	I	1	0	1	3	1
	Nervous system disorders/ Dysgeusia/ METALLIC TASTE	07JAN2013 /136	08JAN2013 /-20	C	1	0	1	3	1
	Nervous system disorders/ Dysgeusia/ METALLIC TASTE	10DEC2012 /108	10DEC2012 /-49	C	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0001/61 /M/W2/N	Nervous system disorders/ Dysgeusia/ METALLIC TASTE	10SEP2012 /17	10SEP2012 /-140	C	1	0	1	3	1
113-0002/64 /F/W2/N	Skin and subcutaneous tissue disorders/ Spider naevus/ FEW SPIDER NEVI ON CHEST	06MAY2013 /203	20MAY2013 /-21	C	1	0	1	4	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	28NOV2012 /44	28NOV2012 /-194	C	1	0	1	3	1
	Skin and subcutaneous tissue disorders/ Spider naevus/ FEW SPIDER NEVI ON CHEST	03JUN2013 /231	24JUN2013 /14	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0002/64 /F/W2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	26NOV2012 /42	26NOV2012 /-196	C	1	0	1	3	1
	Injury, poisoning and procedural complications/ Contusion/ BRUISING - RIGHT UPPER ARM	01APR2013 /168	01MAY2013 /-40	C	1	0	1	4	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	06NOV2012 /22	06NOV2012 /-216	C	1	0	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	03NOV2012 /19	03NOV2012 /-219	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0002/64 /F/W2/N	Injury, poisoning and procedural complications/ Contusion/ BRUISING LEFT UPPER ARM	01APR2013 /168	19APR2013 /-52	C	1	0	1	3	1
	General disorders and administration site conditions/ Fatigue/ TIREDNESS	24OCT2012 /9	29OCT2012 /-224	C	1	0	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	09NOV2012 /25	16NOV2012 /-206	C	1	1	1	3	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	08MAY2013 /205	09MAY2013 /-32	I	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0002/64 /F/W2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	27OCT2012 /12	28OCT2012 /-225	C	1	0	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	30OCT2012 /15	30OCT2012 /-223	C	1	0	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	02NOV2012 /18	02NOV2012 /-220	C	1	0	1	3	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	08MAY2013 /205	09MAY2013 /-32	I	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0002/64 /F/W2/N	Gastrointestinal disorders/ Vomiting/ VOMIT	11NOV2012 /27	11NOV2012 /-211	C	1	0	1	3	1
113-0005/58 /M/W2/N	Hepatobiliary disorders/ Jaundice/ MILD JAUNDICE	12MAR2014 /49	05APR2014 /24	C	1	0	1	3	1
	Injury, poisoning and procedural complications/ Rib fracture/ FRACTURED RIB	26JAN2014 /4	21FEB2014 /-19	C	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Urticaria/ HIVES	22FEB2014 /31	27FEB2014 /-13	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0005/58 /M/W2/N	Investigations/ Blood pressure increased/ INCREASED BLOOD PRESSURE AFTER INJECTION	22JAN2014 /0	30JAN2014 /-41	I	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	13MAR2014 /50	20MAR2014 /8	C	1	0	1	4	3
113-0008/78 /M/A8/N	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCENPHALOPATHY	16FEB2014 /3	20FEB2014 /7	C	1	1	1	4 [CD]	3
113-0010/59 /M/W2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	19MAY2014 /21	19MAY2014 /-4	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0010/59 /M/W2/N	Gastrointestinal disorders/ Vomiting/ VOMITING	19MAY2014 /21	19MAY2014 /-4	I	1	0	1	4	1
113-0013/56 /M/W2/N	Nervous system disorders/ Burning sensation/ BILATERAL BURNING SENSATION IN HANDS	06DEC2014 /32	06JAN2015 /-6	C	1	0	1	4	1
	Gastrointestinal disorders/ Toothache/ PAIN IN RIGHT FRONT TOOTH	12JAN2015 /69	26JAN2015 /14	C	1	0	1	5	1
	Infections and infestations/ Hordeolum/ STYE IN RIGHT EYE	09JAN2015 /66	26JAN2015 /14	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0013/56 /M/W2/N	Infections and infestations/ Rhinitis/ RHINITIS	13DEC2014 /39	26JAN2015 /14	C	1	0	1	4	1
113-0016/72 /M/A8/N	General disorders and administration site conditions/ Injection site erythema/ ERYTHEMATOUS RASH AT INJECTION SITE ON BOTH ARMS	18FEB2015 /15	19FEB2015 /-55	C	1	1	1	2	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	28FEB2015 /25	28FEB2015 /-46	I	1	1	1	4	1
114-0003/59 /M/W2/N	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	12DEC2012 /13	26DEC2012 /-105	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
114-0003/59 /M/W2/N	Metabolism and nutrition disorders/ Gout/ WORSENING GOUT	26DEC2012 /27	Unknown/NA	I	6	1	1	5	1
	Eye disorders/ Glaucoma/ GLAUCOMA	01DEC2012 /2	Unknown/NA	C	6	1	1	5	1
114-0005/73 /M/W2/N	Musculoskeletal and connective tissue disorders/ Pain in extremity/ PAIN IN EXTREMITY - LEFT ARM	22JAN2014 /42	Unknown/NA	C	6	0	1	3	1
114-0007/60 /F/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	02APR2015 /134	Unknown/NA	C	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
114-0007/60 /F/W2/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	01JAN2015 /43	Unknown/NA	I	6	0	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	21JAN2015 /63	Unknown/NA	I	6	0	1	3	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	08JAN2015 /50	Unknown/NA	I	6	0	1	3	1
	Immune system disorders/ Hypersensitivity/ ALLERGIC REACTION	29DEC2014 /40	Unknown/NA	I	6	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
114-0007/60 /F/W2/N	Infections and infestations/ Rhinitis/ RHINITIS	19FEB2015 /92	24FEB2015 /-133	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	24FEB2015 /97	26FEB2015 /-131	C	1	0	1	3	1
	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER ABDOMINAL QUADRANT PAIN	17MAR2015 /118	Unknown/NA	I	6	0	1	3	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	24FEB2015 /97	26FEB2015 /-131	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
114-0007/60 /F/W2/N	Gastrointestinal disorders/ Dysphagia/ DIFFICULTY SWALLOWING	01JAN2015 /43	Unknown/NA	I	6	0	1	3	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	28MAR2015 /129	28MAR2015 /-101	I	1	0	1	3	3
	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	29DEC2014 /40	29DEC2014 /-190	C	1	0	1	4	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	17MAR2015 /118	Unknown/NA	I	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
114-0007/60 /F/W2/N	Infections and infestations/ Nasopharyngitis/ RESPIRATORY OTHERB - COLD	27JUN2015 /220	02JUL2015 /-5	C	1	0	1	5	1
115-0001/59 /F/A4/Y	Immune system disorders/ Hypersensitivity/ ALLERGIC REACTION	27NOV2012 /0	14FEB2013 /9	I	1	1	1	1	2
115-0002/45 /F/W2/N	Vascular disorders/ Embolism/ THROMBOEMBOLIC EVENT	10JAN2013 /44	Unknown/NA	C	6	1	1	5	3
	General disorders and administration site conditions/ Oedema peripheral/ WORSENING EDEMA LIMBS	11DEC2012 /14	18DEC2012 /-21	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
115-0002/45 /F/W2/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	26DEC2012 /29	Unknown/NA	C	6	0	1	5	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	28NOV2012 /1	Unknown/NA	I	6	1	1	4	2
	Gastrointestinal disorders/ Ascites/ ASCITES	11DEC2012 /14	27DEC2012 /-12	C	1	1	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ WORSENING EDEMA LIMBS	26DEC2012 /29	02JAN2013 /-6	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
115-0002/45 /F/W2/N	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	06DEC2012 /9	Unknown/NA	I	6	1	1	4	1
	Psychiatric disorders/ Confusional state/ CONFUSION	31DEC2012 /34	02JAN2013 /-6	C	1	1	3 /02JAN2013 /08JAN2013	5	3
115-0003/63 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	14MAR2013 /56	Unknown/NA	C	6	0	1	4	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL BLOATING	16MAY2013 /119	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
115-0003/63 /M/W2/N	Blood and lymphatic system disorders/ Leukocytosis/ LEUKOCYTOSIS	24JUN2013 /158	01JUL2013 /0	C	1	1	1	5	3
	General disorders and administration site conditions/ Oedema peripheral/ LOWER EXTREMITY EDEMA	13JUN2013 /147	Unknown/NA	C	6	0	1	4	1
	Metabolism and nutrition disorders/ Hypoglycaemia/ HYPOGLYCEMIA	01FEB2013* /15	Unknown/NA	I	6	1	1	3	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	18APR2013 /91	Unknown/NA	C	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
115-0003/63 /M/W2/N	Nervous system disorders/ Neuropathy peripheral/ PERIPHERAL NEUROPATHY	13JUN2013 /147	Unknown/NA	C	6	0	1	4	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	07FEB2013 /21	14FEB2013 /-137	I	1	1	3 /07FEB2013 /14FEB2013	2	3
	Psychiatric disorders/ Depression/ DEPRESSION	30MAY2013 /133	Unknown/NA	I	6	1	1	5	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	28FEB2013 /42	07MAR2013 /-116	I	1	1	3 /28FEB2013 /07MAR2013	2	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
115-0003/63 /M/W2/N	Nervous system disorders/ Balance disorder/ DYSEQUILIBRIUM	16MAY2013 /119	Unknown/NA	I	6	0	1	5	1
	Gastrointestinal disorders/ Ascites/ ASCITES	25JUN2013 /159	Unknown/NA	C	6	1	1	4	2
115-0008/51 /M/A8/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	19JUN2013 /0	19JUN2013 /-13	I	1	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	08JUL2013 /19	08JUL2013 /6	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
115-0008/51 /M/A8/Y	Gastrointestinal disorders/ Vomiting/ VOMITING	19JUN2013 /0	Unknown/NA	I	6	3	1	3	1
	Nervous system disorders/ Hepatic encephalopathy/ INTERMITTENT HEPATIC ENCEPHALOPATHY	27JUN2013 /8	Unknown/NA	I	6	1	1	5	2
	General disorders and administration site conditions/ Disease progression/ DISEASE PROGRESSION	17JUL2013 /28	17JUL2013 /15	C	4	0	1	5 [PD]	5
115-0009/85 /M/W2/N	Hepatobiliary disorders/ Biliary colic/ BILIARY COLIC	08JAN2014 /27	09JAN2014 /-126	C	1	3	3 /09JAN2014 /16JAN2014	4 [Flare Up Of Medical History Event - Recurrent Gallstones Now S/P Cholecystec tomy]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
115-0009/85 /M/W2/N	Gastrointestinal disorders/ Ascites/ WORSENING ASCITES	08JAN2014 /27	Unknown/NA	I	6	2	1	4	3
	General disorders and administration site conditions/ Oedema peripheral/ LOWER EXTREMITY EDEMA	26DEC2013 /14	Unknown/NA	C	6	0	1	5	2
	Metabolism and nutrition disorders/ Hyperkalaemia/ INTERMITTENT HYPERKALEMIA	28JAN2014 /47	Unknown/NA	I	6	0	1	5	2
	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	17FEB2014 /67	19FEB2014 /-85	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
115-0009/85 /M/W2/N	Gastrointestinal disorders/ Ascites/ ASCITES	26DEC2013 /14	08JAN2014 /-127	C	3	0	1	4	1
	Injury, poisoning and procedural complications/ Avulsion fracture/ AVULSION FRACTURE	16APR2014 /125	Unknown/NA	C	6	0	1	4	2
115-0011/56 /M/W2/N	Renal and urinary disorders/ Nocturia/ INTERMITTENT NOCTURIA	13JUN2014 /7	Unknown/NA	I	6	0	1	4	1
	Gastrointestinal disorders/ Nausea/ INTERMITTENT NAUSEA	13JUN2014 /7	Unknown/NA	I	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
115-0011/56 /M/W2/N	Blood and lymphatic system disorders/ Thrombocytopenia/ WORSENING THROMBOCYTOPENIA	20JUN2014 /14	26JUN2014 /-63	C	1	0	3 /20JUN2014 /26JUN2014	2	3
	Psychiatric disorders/ Attention deficit/hyperactivity disorder/ INTERMITTENT ATTENTION DEFICIT	13JUN2014 /7	Unknown/NA	I	6	0	1	5	1
	Skin and subcutaneous tissue disorders/ Urticaria/ HIVES	01AUG2014* /56	Unknown/NA	I	6	0	1	4	1
	General disorders and administration site conditions/ Oedema peripheral/ LOWER EXTREMITY EDEMA	26JUN2014 /20	28AUG2014 /0	I	1	2	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
115-0014/72 /M/W2/N	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT PAIN	24MAR2015 /42	Unknown/NA	C	6	0	1	4	1
	Gastrointestinal disorders/ Rectal haemorrhage/ RECTAL BLEEDING	23MAR2015 /41	Unknown/NA	C	6	0	1	5	1
	Nervous system disorders/ Dizziness/ LIGHT HEADEDNESS	10MAR2015 /28	Unknown/NA	I	6	0	1	4	1
	Renal and urinary disorders/ Renal failure/ RENAL INSUFFICIENCY	18FEB2015 /8	Unknown/NA	C	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
115-0014/72 /M/W2/N	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	17MAR2015 /35	Unknown/NA	C	6	1	1	4	1
	Renal and urinary disorders/ Nocturia/ NOCTURIA	09MAR2015 /27	10MAR2015 /-7	I	1	0	1	4	1
	General disorders and administration site conditions/ Fatigue/ WORSENING FATIGUE	23MAR2015 /41	Unknown/NA	C	6	0	3 /24MAR2015 /Unknown	4	2
	Gastrointestinal disorders/ Ascites/ WORSENING ASCITES	18FEB2015 /8	Unknown/NA	C	6	2	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
115-0014/72 /M/W2/N	Gastrointestinal disorders/ Dry mouth/ XEROSTOMIA	10MAR2015 /28	Unknown/NA	C	6	0	1	2	1
	Injury, poisoning and procedural complications/ Incision site complication/ RUQ INCISION DISCOMFORT	10MAR2015 /28	Unknown/NA	C	6	0	1	5	1
116-0002/67 /F/W2/N	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ PAIN BILATERAL SUBCOSTAL MARGINS	18NOV2013 /245	14DEC2013 /33	C	1	0	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA (LOWER EXTREMITIES)	03JUN2013 /77	14DEC2013 /33	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
116-0002/67 /F/W2/N	Skin and subcutaneous tissue disorders/ Rash erythematous/ ERYTHEMATOUS RASH ON BACK	03JUN2013 /77	17JUN2013 /-147	I	1	0	1	5[Unknown Etiology]	1
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	01JUL2013 /105	14DEC2013 /33	I	1	1	1	5	4
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL BLOATING	08APR2013 /21	14DEC2013 /33	C	1	0	1	5[Ascites/E tiology Unknown]	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	25MAR2013 /7	09JUN2013 /-155	C	1	0	1	5[CD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
116-0002/67 /F/W2/N	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	17JUN2013 /91	02DEC2013 /21	C	1	1	1	4	2
	Metabolism and nutrition disorders/ Hypercalcaemia/ HYPERCALCEMIA	09SEP2013 /175	16SEP2013 /-56	C	1	1	1	5	4
	Gastrointestinal disorders/ Ascites/ ABDOMINAL ASCITES	25APR2013 /38	14DEC2013 /33	C	1	1	1	5	2
	Gastrointestinal disorders/ Abdominal distension/ WORSENING ABDOMINAL DISTENSION	20MAY2013 /63	17JUN2013 /-147	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
116-0002/67 /F/W2/N	General disorders and administration site conditions/ Injection site reaction/ INJECTION SITE REACTION	08APR2013 /21	15APR2013 /-210	C	1	0	1	3	1
	Blood and lymphatic system disorders/ Anaemia/ WORSENING ANEMIA	10JUN2013 /84	17JUN2013 /-147	C	1	1	1	4	3
	Psychiatric disorders/ Depression/ DEPRESSION	25MAR2013 /7	01APR2013 /-224	I	1	0	1	5[Etiology Unknown]	2
	Gastrointestinal disorders/ Small intestinal haemorrhage/ ILEAL HEMMORRHAGE (FROM ILEOSTOMY)	21OCT2013 /217	25OCT2013 /-17	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
116-0003/67 /M/BL/N	Gastrointestinal disorders/ Nausea/ NAUSEA	06MAY2013 /39	07MAY2013 /7	I	1	0	1	5[Etiology Unknown]	2
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	25APR2013 /28	29MAY2013 /29	C	1	1	1	5	2
	Investigations/ Blood creatinine increased/ ELEVATED CREATININE	25APR2013 /28	29MAY2013 /29	I	1	0	3 /25APR2013 /30APR2013	5	3
	Cardiac disorders/ Sinus tachycardia/ SINUS TACHYCARDIA	07MAY2013 /40	07MAY2013 /7	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
116-0003/67 /M/BL/N	Gastrointestinal disorders/ Vomiting/ VOMITING	06MAY2013 /39	07MAY2013 /7	I	1	0	1	5[Etiology Unknown]	1
	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINEMIA	25APR2013 /28	29MAY2013 /29	I	1	0	3 /25APR2013 /30APR2013	5	2
	General disorders and administration site conditions/ Fatigue/ WORSENING FATIGUE	07MAY2013 /40	15MAY2013 /15	I	1	0	1	5[Etiology Unknown]	3
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	11APR2013 /14	29MAY2013 /29	I	1	0	1	5[Etiology Unknown]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
116-0003/67 /M/BL/N	Renal and urinary disorders/ Acute kidney injury/ ACUTE RENAL FAILURE	04APR2013 /7	17APR2013 /-13	I	1	0	1	5[Etiology Unknown]	1
	Renal and urinary disorders/ Acute kidney injury/ ACUTE RENAL FAILURE	18APR2013 /21	29MAY2013 /29	I	1	0	1	5[CM]	2
	Gastrointestinal disorders/ Ascites/ ASCITES	28MAR2013 /0	24APR2013 /-6	C	3	1	1	5	2
	General disorders and administration site conditions/ Fatigue/ WORSENING FATIGUE	23MAY2013 /56	29MAY2013 /29	I	1	0	1	5[CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
116-0003/67 /M/BL/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	25APR2013 /28	29MAY2013 /29	C	1	0	3 /25APR2013 /30APR2013	5[Adverse Event (Ascites)]	1
	Gastrointestinal disorders/ Abdominal distension/ WORSENING ABDOMINAL DISTENSION	16MAY2013 /49	29MAY2013 /29	C	1	2	3 /09MAY2013 /22MAY2013	5[CD]	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	16MAY2013 /49	22MAY2013 /22	C	1	0	3 /09MAY2013 /22MAY2013	5[Etiology Unknown]	2
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT NEOPLASM PROGRESSION	23MAY2013 /56	29MAY2013 /29	C	4	0	1	5[PD]	5

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
116-0003/67 /M/BL/N	Gastrointestinal disorders/ Ascites/ WORSENING ABDOMINAL ASCITES	25APR2013 /28	29MAY2013 /29	C	1	2	3 /25APR2013 /30APR2013	5	3
	Psychiatric disorders/ Confusional state/ CONFUSION	16MAY2013 /49	23MAY2013 /23	I	1	0	3 /09MAY2013 /22MAY2013	5[Etiology Unknown]	1
	Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	07MAY2013 /40	07MAY2013 /7	C	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	25APR2013 /28	16MAY2013 /16	I	1	1	3 /25APR2013 /30APR2013	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
116-0003/67 /M/BL/N	Gastrointestinal disorders/ Abdominal pain/ WORSENING ABDOMINAL PAIN	30APR2013 /33	29MAY2013 /29	I	1	1	1	5[Adverse Event (Ascites)]	1
	Respiratory, thoracic and mediastinal disorders/ Wheezing/ WHEEZING	25APR2013 /28	16MAY2013 /16	I	1	0	3 /25APR2013 /30APR2013	5[Adverse Event]	1
	General disorders and administration site conditions/ Injection site pain/ INJECTION SITE SORENESS	18APR2013 /21	25APR2013 /-5	I	1	0	1	3	2
	Psychiatric disorders/ Confusional state/ WORSENING CONFUSION	23MAY2013 /56	29MAY2013 /29	I	1	0	1	5[Etiology Unknown]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
117-0001/69 /M/W2/N	General disorders and administration site conditions/ Pain/ WORSENING PAIN-RIGHT BACK AND LEG	12APR2013 /10	30JUN2013 /19	I	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ WORSENING LEFT THIGH PAIN	27APR2013 /25	30JUN2013 /19	C	1	1	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LOWER EXTREMITY EDEMA	23APR2013 /21	08NOV2014 /515	C	1	3	1	4	2
	Nervous system disorders/ Paraesthesia/ PARASTHESIA RIGHT THIGH TO ANKLE	12APR2013 /10	08NOV2014 /515	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
117-0001/69 /M/W2/N	Nervous system disorders/ Areflexia/ ABSENT INTRAPATELLAR REFLEX ON RIGHT	23APR2013 /21	08NOV2014 /515	C	1	0	1	4	2
	Injury, poisoning and procedural complications/ Fall/ FALL	29MAY2013 /57	29MAY2013 /-13	I	1	0	1	4	1
	Nervous system disorders/ Areflexia/ ABSENT INTRAPETELLAR REFLEX ON LEFT	04JUN2013 /63	08NOV2014 /515	C	1	0	1	4	2
118-0001/67 /F/A8/Y	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	06MAY2014 /267	09JUL2014 /260	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
118-0001/67 /F/A8/Y	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	09JUL2014 /331	19JUL2014 /270	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	19JUL2014 /341	Unknown/NA	C	6	0	1	5	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	28JAN2014 /169	31MAR2014 /160	C	1	0	1	5	2
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	28JAN2014 /169	31MAR2014 /160	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
118-0001/67 /F/A8/Y	General disorders and administration site conditions/ Nodule/ LEFT FOREARM NODULE	28JAN2014 /169	25FEB2014 /126	C	1	0	1	4	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	31MAR2014 /231	24APR2014 /184	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	31MAR2014 /231	24APR2014 /184	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	26DEC2013 /136	28JAN2014 /98	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
118-0001/67 /F/A8/Y	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	05MAY2014 /266	06MAY2014 /196	C	1	0	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	24APR2014 /255	19JUN2014 /240	C	1	0	1	5	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	19JUL2014 /341	19JUL2014 /270	C	1	0	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	09JUL2014 /331	19JUL2014 /270	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
118-0001/67 /F/A8/Y	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	19JUL2014 /341	Unknown/NA	C	6	0	1	5	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	26DEC2013 /136	28JAN2014 /98	C	1	0	1	5	1
	Investigations/ Platelet count decreased/ DECREASED PLATELETS	10SEP2013 /29	12SEP2013 /-40	C	1	0	3 /10SEP2013 /12SEP2013	2	3
	Investigations/ Blood albumin decreased/ DECREASED ALBUMIN	17SEP2013 /36	21NOV2013 /30	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
118-0001/67 /F/A8/Y	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	19JUN2014 /311	09JUL2014 /260	C	1	0	1	5	1
	Investigations/ Platelet count decreased/ DECREASED PLATELETS	12SEP2013 /31	17SEP2013 /-35	C	1	0	1	2	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	21NOV2013 /101	Unknown/NA	C	6	0	1	5	2
	Investigations/ White blood cell count decreased/ DECREASED WHITE BLOOD CELL COUNT	03SEP2013 /22	10SEP2013 /-42	C	1	0	1	2	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
118-0001/67 /F/A8/Y	Investigations/ Platelet count decreased/ DECREASED PLATELETS	29OCT2013 /78	Unknown/NA	C	6	0	1	3	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	24APR2014 /255	05MAY2014 /195	C	1	0	1	5	2
	Investigations/ Alanine aminotransferase increased/ INCREASED ALT	21NOV2013 /101	26DEC2013 /65	C	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ RIGHT ABDOMINAL PAIN	16AUG2013 /4	21NOV2013 /30	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
118-0001/67 /F/A8/Y	Investigations/ Blood albumin decreased/ DECREASED ALBUMIN	21NOV2013 /101	26DEC2013 /65	C	1	0	1	5	2
	Investigations/ Platelet count decreased/ DECREASED PLATELETS	03OCT2013 /52	17OCT2013 /-5	C	1	0	1	3	1
	Investigations/ Platelet count decreased/ DECREASED PLATELETS	20AUG2013 /8	10SEP2013 /-42	C	1	0	1	4	1
	General disorders and administration site conditions/ Implant site pain/ SLIGHT PAIN (NEAR MEDI-PORT)	26DEC2013 /136	28JAN2014 /98	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
118-0001/67 /F/A8/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	20DEC2013 /130	28JAN2014 /98	I	1	1	1	5	1
	Investigations/ Neutrophil count decreased/ LOW ABSOLUTE NEUTROPHIL COUNT	03SEP2013 /22	10SEP2013 /-42	C	1	1	3 /10SEP2013 /10SEP2013	2	3
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	21NOV2013 /101	26DEC2013 /65	C	1	0	1	5	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	28JAN2014 /169	25FEB2014 /126	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
119-0001/80 /M/A8/N	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	30JAN2014 /9	04FEB2014 /7	C	1	3	2	4 [CD]	3
	General disorders and administration site conditions/ Injection site pain/ PAIN DURING STUDY DRUG INJECTION.	21JAN2014 /0	28JAN2014 /0	I	1	0	1	1	1
	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	28JAN2014 /7	30JAN2014 /2	C	1	0	1	4	2
121-0001/62 /M/W2/N	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	08APR2014 /49	15APR2014 /-21	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
121-0001/62 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	15APR2014 /56	22APR2014 /-14	C	1	0	1	4	1
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	01APR2014 /42	Unknown/NA	I	6	1	1	2	1
	Skin and subcutaneous tissue disorders/ Rash maculo-papular/ RASH (MACULOPAPULAR)	25MAR2014 /35	08APR2014 /-28	C	1	0	1	2	1
	Vascular disorders/ Hot flush/ HOT FLASH	18FEB2014 /0	18FEB2014 /-77	C	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
121-0001/62 /M/W2/N	Gastrointestinal disorders/ Abdominal pain upper/ PAIN (RUQ)	22APR2014 /63	Unknown/NA	C	5	1	1	4	1
	General disorders and administration site conditions/ Injection site pain/ PAIN AT SITE OF INJECTION	18FEB2014 /0	18FEB2014 /-77	I	1	0	1	1	1
201-0001/68 /F/W2/N	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Cancer pain/ WORSENING OF CANCER RELATED PAIN	08FEB2012 /13	23FEB2012 /-56	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	15MAR2012 /49	11APR2012 /-8	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0001/68 /F/W2/N	Investigations/ White blood cell count decreased/ WORSENING WBC DECREASED	29MAR2012 /63	11APR2012 /-8	C	1	0	1	3	2
	Investigations/ Neutrophil count decreased/ ANC DECREASE	29MAR2012 /63	11APR2012 /-8	C	1	0	1	3	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	11APR2012 /76	23MAY2012 /34	C	1	0	1	5	2
	Investigations/ Haemoglobin decreased/ HGB DECREASE	01MAR2012 /35	29MAR2012 /-21	C	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0001/68 /F/W2/N	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Cancer pain/ INCREASE OF WORSENING OF CANCER RELATED PAIN	11APR2012 /76	Unknown/NA	C	6	1	1	5	2
	Investigations/ Platelet count decreased/ PLATELET DECREASE	29MAR2012 /63	11APR2012 /-8	C	1	0	1	3	1
	Investigations/ White blood cell count decreased/ WBC DECREASE	01MAR2012 /35	29MAR2012 /-21	C	1	0	1	3	1
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Cancer pain/ CANCER RELATED PAIN	29MAR2012 /63	11APR2012 /-8	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0001/68 /F/W2/N	Investigations/ Haemoglobin decreased/ DECREASE HGB	11APR2012 /76	23MAY2012 /34	C	1	0	1	3	2
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Cancer pain/ WORSENING OF CANCER RELATED PAIN	23FEB2012 /28	29MAR2012 /-21	C	1	1	1	5	2
	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	06FEB2012 /11	16FEB2012 /-63	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	01MAR2012 /35	15MAR2012 /-35	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0005/73 /M/W2/Y	Investigations/ Blood phosphorus decreased/ BLOOD PHOSPHORUS DECREASE	09AUG2012 /21	08OCT2012 /4	C	1	0	1	3	2
	Vascular disorders/ Hypotension/ ARTERIAL HYPOTENSION	12OCT2012 /85	19OCT2012 /15	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	12OCT2012 /85	19OCT2012 /15	C	1	0	1	5	1
201-0008/79 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	09AUG2013 /85	15OCT2013 /90	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0008/79 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	19JUL2013 /64	09AUG2013 /23	C	1	0	1	3	2
201-0012/79 /M/W2/N	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	06DEC2013 /135	03JAN2014 /-251	C	1	0	1	5	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	03JAN2014 /163	16JAN2014 /-238	C	1	0	1	5	2
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	13MAR2014 /232	27MAR2014 /-168	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0012/79 /M/W2/N	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	30JAN2014 /190	13MAR2014 /-182	C	1	0	1	5	2
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	16JAN2014 /176	30JAN2014 /-224	C	1	0	1	5	1
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	03JUL2014 /344	16JUL2014 /-57	C	1	0	1	5	2
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	15OCT2014 /448	Unknown/NA	C	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0012/79 /M/W2/N	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	27MAR2014 /246	21MAY2014 /-113	C	1	0	1	5	2
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	05JUN2014 /316	28AUG2014 /-14	C	1	0	1	5	2
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	28AUG2014 /400	15OCT2014 /34	C	1	0	1	5	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	12SEP2013 /50	06DEC2013 /-279	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0012/79 /M/W2/N	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	01AUG2013 /8	08AUG2013 /-399	C	1	0	1	5	3
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	16JUL2014 /357	Unknown/NA	C	6	0	1	5	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	29AUG2013 /36	12SEP2013 /-364	C	1	0	1	5	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	21MAY2014 /301	05JUN2014 /-98	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0016/72 /M/W2/N	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	30JAN2014 /77	09APR2014 /-8	C	1	0	1	5	3
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	16JAN2014 /63	30JAN2014 /-77	C	1	0	1	5	2
	Investigations/ White blood cell count decreased/ DECREASE WBC	21NOV2013 /7	28NOV2013 /-140	C	1	1	1	5	3
	Musculoskeletal and connective tissue disorders/ Bone pain/ BONE PAIN (PAIN AT RIGHT CLAVICLE)	03APR2014 /140	Unknown/NA	C	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0016/72 /M/W2/N	Investigations/ Neutrophil count decreased/ DECREASE TOTAL ANC	21NOV2013 /7	28NOV2013 /-140	C	1	1	1	5	3
	Investigations/ White blood cell count decreased/ DECREASE WBC	21MAY2014 /188	Unknown/NA	C	6	0	1	5	4
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	21MAY2014 /188	Unknown/NA	C	6	0	1	5	3
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	21NOV2013 /7	16JAN2014 /-91	C	1	0	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0016/72 /M/W2/N	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	09APR2014 /146	21MAY2014 /34	C	1	0	1	5	2
201-0017/82 /M/W2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	11DEC2013 /13	24DEC2013 /18	C	1	1	1	4	1
	Hepatobiliary disorders/ Hepatic failure/ HEPATIC FAILURE	13DEC2013 /15	24DEC2013 /18	C	1	0	2	3	4
201-0018/78 /F/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	10JAN2014 /35	Unknown/NA	C	6	0	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0018/78 /F/W2/N	Hepatobiliary disorders/ Hepatic failure/ HEPATIC FAILURE	24DEC2013 /18	08JAN2014 /20	C	1	1	1	3	4
	Infections and infestations/ Urinary tract infection bacterial/ URINARY TRACT INFECTION - KLEBSIELLA	08JAN2014 /33	17JAN2014 /29	C	1	1	1	5	2
201-0019/68 /M/W2/N	Musculoskeletal and connective tissue disorders/ Pain in extremity/ PAIN IN EXTREMITY (PAIN AT LEFT ARM)	28FEB2014 /71	Unknown/NA	C	6	1	1	5	1
201-0020/67 /M/W2/N	Immune system disorders/ Hypersensitivity/ ALLERGIC REACTION (IMMUNO SYSTEM DISORDER)	30JAN2014 /7	30JAN2014 /0	C	1	1	2	1	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0021/54 /M/W2/N	Investigations/ Blood urea increased/ INCREASE BUN (17.0 MCNMOL/L)	04JUN2014 /111	Unknown/NA	C	6	0	1	5	
	Investigations/ Blood bilirubin increased/ INCREASE BILIRUBIN	04JUN2014 /111	Unknown/NA	C	6	0	1	5	4
	Investigations/ Blood sodium decreased/ DECREASE SODIUM	04JUN2014 /111	Unknown/NA	C	6	0	1	5	3
	Investigations/ Haemoglobin decreased/ DECREASE HGB	04JUN2014 /111	Unknown/NA	C	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0021/54 /M/W2/N	Blood and lymphatic system disorders/ Leukocytosis/ LEUKOCYTOSIS (WBC 17.56 GI/L)	04JUN2014 /111	Unknown/NA	C	6	0	1	5	
	Investigations/ Neutrophil count increased/ INCREASE TOTAL ANC (14.59 GI/L)	04JUN2014 /111	Unknown/NA	C	6	0	1	5	
201-0024/74 /M/W2/Y	Vascular disorders/ Hypertension/ ARTERIAL HYPERTENSION	29JAN2015 /0	05FEB2015 /-34	C	1	1	1	4	2
	Vascular disorders/ Hypertension/ ARTERIAL HYPERTENSION	05FEB2015 /7	Unknown/NA	C	6	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0024/74 /M/W2/Y	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	19FEB2015 /21	Unknown/NA	C	6	1	1	5	1
201-0025/75 /M/W2/N	Hepatobiliary disorders/ Hepatic failure/ HEPATIC FAILURE (ENCEPHALOPATHY)	14FEB2015 /16	23FEB2015 /10	C	1	1	1	3	3
203-0001/61 /F/W2/N	Gastrointestinal disorders/ Lip oedema/ EDEMA OF THE LIPS	13APR2012 /38	15APR2012 /2	C	1	1	1	2	1
	Skin and subcutaneous tissue disorders/ Rash/ GROIN RASH	11APR2012 /36	13APR2012 /0	C	1	1	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0001/61 /F/W2/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DISPNOEA	30APR2012 /55	Unknown/NA	C	6	1	1	5	1
	General disorders and administration site conditions/ Injection site erythema/ CUTANEOUS REACTION (ERYTHEMA ) IN SITE STUDY DRUG INJECTION	14MAR2012 /8	21MAR2012 /-23	C	1	1	3 /15MAR2012 /22MAR2012	4	1
	Skin and subcutaneous tissue disorders/ Rash/ THIGHS RASH	11APR2012 /36	13APR2012 /0	I	3	1	1	2	1
	Skin and subcutaneous tissue disorders/ Erythema/ ERITEMA	14MAR2012 /8	14MAR2012 /-30	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0001/61 /F/W2/N	General disorders and administration site conditions/ Oedema peripheral/ EDEMA OF THE LEGS	01APR2012* /26	Unknown/NA	C	6	1	1	5	1
	Gastrointestinal disorders/ Varices oesophageal/ VARICES ESOPHAGEAL	11APR2012 /36	Unknown/NA	C	6	0	1	5	1
	General disorders and administration site conditions/ Face oedema/ EDEMA OF THE FACE	13APR2012 /38	15APR2012 /2	C	1	1	2	2	3
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ BREATHING DIFFICULTY	13APR2012 /38	15APR2012 /2	C	1	1	1	2	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0001/61 /F/W2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	13MAR2012 /7	20MAR2012 /-24	C	1	1	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	23MAR2012 /17	27MAR2012 /-17	C	1	1	1	2	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	23MAR2012 /17	27MAR2012 /-17	C	1	1	1	5	1
	General disorders and administration site conditions/ General physical health deterioration/ DETERIORATION OF HEALTH CONDITIONS	30APR2012 /55	Unknown/NA	C	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0002/72 /M/W2/N	General disorders and administration site conditions/ General physical health deterioration/ GENERAL CLINICAL CONDITION DETERIORATION	19APR2012 /44	19APR2012 /8	C	4	0	2	5 [PD]	5
	Renal and urinary disorders/ Dysuria/ BURNING WITH URINATION	06MAR2012* /0	31MAR2012* /-11	C	3	0	1	5	1
	Skin and subcutaneous tissue disorders/ Erythema/ RIGHT LEG REDNESS	30MAR2012 /24	30MAR2012 /-12	C	1	1	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ RIGHT LEG EDEMA	30MAR2012 /24	30MAR2012 /-12	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0002/72 /M/W2/N	Investigations/ Urine output decreased/ DECREASED URINARY EXCRETION	10APR2012 /35	19APR2012 /8	C	1	1	1	5 [CD]	3
	General disorders and administration site conditions/ Fatigue/ WORSENING FATIGUE	06MAR2012* /0	19APR2012 /8	C	3	0	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ DETERIORATION OF LEGS EDEMA	10APR2012 /35	19APR2012 /8	C	1	1	1	5 [CD]	3
	General disorders and administration site conditions/ Pyrexia/ FEVER	06MAR2012 /0	11MAR2012 /-31	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0002/72 /M/W2/N	Musculoskeletal and connective tissue disorders/ Mobility decreased/ DIFFICULTY TO MOVE LEGS	10APR2012 /35	19APR2012 /8	C	1	1	1	5 [CD]	3
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYPSPNEA	06MAR2012* /0	09APR2012 /-2	C	1	0	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ LEGS EDEMA	25MAR2012 /19	09APR2012 /-2	C	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ WORSENING DYPSPNEA	10APR2012 /35	19APR2012 /8	C	1	1	1	5 [CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0005/53 /M/W2/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	16APR2012 /11	Unknown/NA	C	6	1	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ ARMS PRURITUS	15MAY2012 /40	15MAY2012 /-51	C	1	1	1	2	1
	Skin and subcutaneous tissue disorders/ Rash/ ARMS RASH	15MAY2012 /40	15MAY2012 /-51	C	1	1	1	2	1
	Vascular disorders/ Hypertension/ HYPERTENSION	27APR2012 /22	Unknown/NA	C	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0005/53 /M/W2/N	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	16APR2012 /11	20APR2012 /-76	C	1	1	3 /17APR2012 /04MAY2012	3	4
	General disorders and administration site conditions/ Pyrexia/ FEVER	20APR2012 /15	31MAY2012* /-35	C	1	1	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	21APR2012 /16	31MAY2012* /-35	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	20APR2012 /15	31MAY2012* /-35	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0005/53 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Dysphonia/ DISFONIA	01MAY2012* /26	Unknown/NA	C	6	0	1	5	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	27APR2012 /22	31MAY2012* /-35	C	1	1	1	5	1
	Skin and subcutaneous tissue disorders/ Rash/ ARMS RASH	04MAY2012 /29	04MAY2012 /-62	I	1	1	1	2	2
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ WORSENING DYPNEA	27APR2012 /22	Unknown/NA	C	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0005/53 /M/W2/N	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL BLOATING	21APR2012 /16	31MAY2012* /-35	I	1	0	1	5	1
	Psychiatric disorders/ Anxiety/ ANXIETY	16APR2012 /11	18APR2012 /-78	C	1	1	1	5	1
203-0013/68 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ LEGS EDEMA	08JAN2014 /9	15JAN2014 /-7	C	1	1	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	16JAN2014 /17	Unknown/NA	C	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0013/68 /M/W2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	16JAN2014 /17	Unknown/NA	I	6	1	1	5	1
	Gastrointestinal disorders/ Ascites/ ASCITES	27JAN2014 /28	Unknown/NA	C	6	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT HYPOCONDRIUM PAIN	08JAN2014 /9	Unknown/NA	C	6	1	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	09JAN2014 /10	10JAN2014 /-12	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0013/68 /M/W2/N	Hepatobiliary disorders/ Portal vein thrombosis/ PORTAL THROMBOSIS	22JAN2014 /23	Unknown/NA	C	6	0	1	5	2
203-0015/85 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ LEGS EDEMA	04APR2014 /64	14APR2014 /10	C	1	0	1	5	1
	General disorders and administration site conditions/ Asthenia/ ASTENIA	14APR2014 /74	Unknown/NA	C	6	0	1	5	1
	Hepatobiliary disorders/ Portal vein thrombosis/ NEOPLASTIC PORTAL THROMBOSIS	04APR2014 /64	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0015/85 /M/W2/N	Investigations/ Weight decreased/ WEIGHT LOSS	14APR2014 /74	Unknown/NA	C	6	0	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ LEGS PRURITUS	25FEB2014 /26	28FEB2014 /-35	C	1	0	1	5	1
	Gastrointestinal disorders/ Ascites/ ASCITES	04APR2014 /64	14APR2014 /10	C	1	1	1	5	1
	Infections and infestations/ Pharyngitis/ PHARYNGITIS	28FEB2014 /29	12MAR2014 /-23	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0015/85 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Epistaxis/ EPISTAXIS	01FEB2014* /2	24FEB2014 /-39	I	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	21MAR2014 /50	23MAR2014 /-12	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ LOW APPETITE	14APR2014 /74	Unknown/NA	C	6	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	04APR2014 /64	Unknown/NA	C	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0015/85 /M/W2/N	Investigations/ Weight increased/ WEIGHT INCREASED	04APR2014 /64	13APR2014 /9	C	1	0	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ LEGS EDEMA	25FEB2014 /26	28FEB2014 /-35	C	1	0	1	5	1
203-0017/58 /M/W2/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	12MAR2014 /9	Unknown/NA	C	6	0	1	5	1
	Nervous system disorders/ Headache/ HEADACHE	12MAR2014 /9	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0017/58 /M/W2/Y	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASE	13MAR2014 /10	07APR2014 /26	C	1	3	2	5[Hepatocel lular Carcinoma]	3
	General disorders and administration site conditions/ Fatigue/ FATIGUE	12MAR2014 /9	Unknown/NA	C	6	0	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ LOW APPETITE	12MAR2014 /9	Unknown/NA	C	6	0	1	5	1
	Gastrointestinal disorders/ Dyspepsia/ DYSPEPSIA	12MAR2014 /9	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0018/58 /F/W2/N	Gastrointestinal disorders/ Vomiting/ VOMITING	15APR2014 /11	15APR2014 /-57	C	1	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	15APR2014 /11	18APR2014 /-54	C	1	0	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ LIMBS EDEMA	21JUN2014 /78	09JUL2014 /28	C	1	0	1	5[Clinical Deteriorati on]	3
	Gastrointestinal disorders/ Haemorrhoids/ HEMORRHOIDS	14APR2014 /10	Unknown/NA	C	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0018/58 /F/W2/N	General disorders and administration site conditions/ Oedema peripheral/ LEGS EDEMA	14APR2014 /10	20JUN2014 /9	C	1	1	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	04APR2014 /0	13APR2014 /-59	C	3	0	1	5	1
	General disorders and administration site conditions/ Generalised oedema/ GENERALIZED EDEMA	21JUN2014 /78	09JUL2014 /28	C	1	0	2	5[Clinical Deteriorati on]	3
	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINEMIA	21JUN2014 /78	09JUL2014 /28	C	1	0	1	5[Clinical Deteriorati on]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0018/58 /F/W2/N	Musculoskeletal and connective tissue disorders/ Muscle spasms/ LEGS CRAMPS	05JUN2014 /62	05JUN2014 /-6	C	1	0	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	21JUN2014 /78	09JUL2014 /28	C	1	1	1	5[Clinical Deteriorati on]	3
	Gastrointestinal disorders/ Vomiting/ VOMITING	02JUN2014 /59	11JUN2014 /0	I	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Erythema/ LEGS AND BACK ERYTHEMA	22APR2014 /18	Unknown/NA	C	6	1	3 /23APR2014 /05MAY2014	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0001/77 /M/W2/N	Infections and infestations/ Clostridium difficile colitis/ CLOSTRIDIUM DIFFICILE COLITIS	15MAR2012 /20	19MAR2012 /-561	C	1	1	1	4	2
	Blood and lymphatic system disorders/ Increased tendency to bruise/ TENDENCY TO DEVELOP HEMATOMAS IN CASE OF LIGHT CONTACT WITH HARD OBJECTS	06JUL2012 /133	07SEP2012 /-389	C	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ MUSCULOSKELETAL CHEST PAIN LEFT SIDE	13APR2012 /49	13JUN2012 /-475	I	1	0	1	5	1
	Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	08MAR2012 /13	15MAR2012 /-565	I	1	1	1	4[Evaluatio n For Correlation To Previous Sae (Pneumonia) ]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0001/77 /M/W2/N	Investigations/ Blood albumin decreased/ ALBUMIN DECREASE	30MAR2012 /35	27APR2012 /-522	C	1	0	1	4	2
	Infections and infestations/ Pneumonia/ PNEUMONIA	29FEB2012 /5	20MAR2012 /-560	C	1	1	3 /29FEB2012 /14MAR2012	4 [Not Known]	3
	Investigations/ Blood albumin decreased/ ALBUMIN DECREASE	27APR2012 /63	08MAY2012 /-511	C	1	0	1	4	1
	Nervous system disorders/ Headache/ HEAD ACHE	13APR2012 /49	20APR2012 /-529	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0001/77 /M/W2/N	Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT THIGH PAIN	01SEP2012* /190	29OCT2012 /-337	C	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Alopecia/ HAIR LOSS	22JUN2012 /119	Unknown/NA	C	6	0	1	3	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	14MAR2012 /19	22MAR2012 /-558	C	1	1	1	2	2
	Investigations/ Blood creatinine increased/ CREATININE INCREASE	14MAR2012 /19	30MAR2012 /-550	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0001/77 /M/W2/N	General disorders and administration site conditions/ Injection site pain/ PAIN AT SITE OF INJECTION	05APR2012 /41	13APR2012 /-536	C	1	0	1	1	1
	Investigations/ Weight decreased/ WEIGHT LOSS	30MAR2012 /35	17MAY2012 /-502	C	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Drug eruption/ LIGHT ALLERGIC REACTION (RASH) DUE TO IBUSTRIN	24MAR2012 /29	19APR2012 /-530	C	1	0	1	5	1
	General disorders and administration site conditions/ Chills/ SHIVER WITHOUT FEVER	02FEB2013 /344	02FEB2013 /-241	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0001/77 /M/W2/N	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	07MAY2012 /73	09MAY2012 /-510	C	1	1	3 /08MAY2012 /11MAY2012	3	3
	General disorders and administration site conditions/ Injection site pain/ PAIN AT SITE OF INJECTION	27APR2012 /63	08MAY2012 /-511	C	1	0	1	1	1
	Gastrointestinal disorders/ Abdominal distension/ METEORISM	01JAN2013* /312	07MAR2013 /-208	I	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ PAIN IN RIGHT HYPOCHONDRUM REGION	25NOV2012 /275	04DEC2012 /-301	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0001/77 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	10JAN2013 /321	24JAN2013 /-250	C	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ STITCH TO RIGHT HIP	01JAN2013* /312	24JAN2013 /-250	I	1	0	1	5	1
	General disorders and administration site conditions/ Asthenia/ ASTHENIA	30MAR2012 /35	Unknown/NA	C	6	0	1	5	1
	Investigations/ Blood uric acid increased/ ACID URIC INCREASE	01MAR2012 /6	Unknown/NA	C	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0001/77 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ LEG EDEMA	02MAR2012 /7	12MAR2012 /-568	C	1	1	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	01AUG2013* /524	Unknown/NA	I	6	0	1	5[Disease Condition]	1
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Basal cell carcinoma/ BASOCELLULAR CARCINOMA ON RIGHT PART OF NOSE (ALA NASI)	30OCT2012 /249	30OCT2012 /-336	C	1	1	1	5	2
	General disorders and administration site conditions/ Injection site erythema/ 10-CM-LARGE CUTANEOUS REACTION AT SITE OF INJECTION, WITH RUBOR	03JUL2012 /130	13JUL2012 /-445	C	1	1	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0001/77 /M/W2/N	Nervous system disorders/ Dysgeusia/ DISGEUSIA	25NOV2012 /275	05DEC2012 /-300	C	1	0	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	25NOV2012 /275	04DEC2012 /-301	C	1	0	1	5	1
	General disorders and administration site conditions/ Injection site pain/ LIGHT PAIN AT SITE OF INJECTION	03JUL2012 /130	13JUL2012 /-445	C	1	1	1	1	1
	Investigations/ Electrocardiogram QT prolonged/ PROLONGED QT	08MAY2012 /74	Unknown/NA	C	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0001/77 /M/W2/N	Gastrointestinal disorders/ Eructation/ ERUCTATION	10JAN2013 /321	24JAN2013 /-250	I	1	1	1	5	1
	General disorders and administration site conditions/ Injection site reaction/ 10-CM-LARGE CUTANEOUS REACTION AT SITE OF INJECTION	03JUL2012 /130	13JUL2012 /-445	C	1	1	1	1	1
	Gastrointestinal disorders/ Anal pruritus/ PERIANAL PRURITUS	22JUN2012 /119	10AUG2012 /-417	I	1	1	1	3	1
	Gastrointestinal disorders/ Dyspepsia/ DYSPEPSIA	01JAN2013* /312	21JAN2013 /-253	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0001/77 /M/W2/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	24AUG2012 /182	Unknown/NA	C	6	1	1	5	1
205-0004/77 /F/W2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	31MAR2012 /11	31MAR2012 /-66	C	1	0	1	2	1
	Gastrointestinal disorders/ Ascites/ ASCITES	04APR2012 /15	Unknown/NA	C	6	0	1	4	1
	Infections and infestations/ Escherichia urinary tract infection/ URINARY TRACT INFECTION (E. COLI)	10MAY2012 /51	16MAY2012 /-20	C	1	3	3 /10MAY2012 /16MAY2012	5[Probably Dehidratati on And Liquid Accumulatio n Due To Cirrhosis.]	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0004/77 /F/W2/N	Metabolism and nutrition disorders/ Polydipsia/ POLIDYPSIA	01APR2012* /12	31MAY2012 /-5	I	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEG PAIN	01APR2012* /12	Unknown/NA	C	6	1	1	5	1
	Skin and subcutaneous tissue disorders/ Rash/ LEG RASH	01APR2012* /12	19APR2012 /-47	C	1	0	1	4	1
	Psychiatric disorders/ Confusional state/ MINIMAL CONFUSION	10MAY2012 /51	31MAY2012 /-5	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0004/77 /F/W2/N	Nervous system disorders/ Psychomotor skills impaired/ PSYCHOMOTOR IMPAIRMENT	04APR2012 /15	05JUN2012 /0	C	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Muscle spasms/ NOCTURNAL LEG CRAMPS	30MAR2012 /10	04APR2012 /-62	C	1	1	1	4	1
	General disorders and administration site conditions/ Oedema peripheral/ WORSENING OF LEG EDEMA	31MAY2012 /72	Unknown/NA	C	6	1	1	5	2
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	31MAY2012 /72	05JUN2012 /0	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0004/77 /F/W2/N	Investigations/ Haemoglobin decreased/ LOW HEMOGLOBIN	10MAY2012 /51	24MAY2012 /-12	C	1	3	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	03APR2012 /14	04APR2012 /-62	C	1	3	3 /04APR2012 /12APR2012	4	3
	Cardiac disorders/ Palpitations/ PALPITATIONS	01APR2012 /12	03MAY2012 /-33	C	1	0	1	5	1
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ PROGRESSION OF LIVER NEOPLASTIC DISEASE: ABDOMEN (LIVER AND MACROSCOPIC VASCULAR INVASION, NODES), LUNG	22JUN2012 /94	24JUN2012 /19	C	4	0	1	5 [PD]	5

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0004/77 /F/W2/N	Cardiac disorders/ Dilatation ventricular/ LEFT VENTRICULAR DILATATION	03MAY2012 /44	Unknown/NA	C	6	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	13MAY2012 /54	13MAY2012 /-23	C	1	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ NOCTURNAL LEG PAIN	30MAR2012 /10	04APR2012 /-62	C	1	1	1	4	1
	Nervous system disorders/ Dizziness/ DIZZINESS	12JUN2012 /84	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0004/77 /F/W2/N	Nervous system disorders/ Asterixis/ LIGHT FLAPPING TREMOR	26APR2012 /37	03MAY2012 /-33	C	1	0	1	5	1
	Investigations/ Blood albumin decreased/ ALBUMIN DECREASE	10MAY2012 /51	Unknown/NA	C	6	3	1	5	1
	Musculoskeletal and connective tissue disorders/ Muscle spasms/ LEG CRAMPS	01APR2012* /12	Unknown/NA	C	6	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	05APR2012 /16	Unknown/NA	C	6	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0004/77 /F/W2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	07APR2012 /18	10MAY2012 /-26	C	1	0	1	3	1
205-0008/76 /M/W2/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	22MAY2012 /25	30JUN2012* /51	C	1	0	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	22MAY2012 /25	Unknown/NA	I	6	1	1	3	1
	Gastrointestinal disorders/ Dyspepsia/ DISPEPSY	10MAY2012 /13	31MAY2012* /21	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0008/76 /M/W2/N	Investigations/ Blood bilirubin increased/ HIGH BILIRUBIN	17MAY2012 /20	Unknown/NA	C	6	0	1	5	2
	Investigations/ White blood cell count decreased/ LOW LEVEL OF WBC	17MAY2012 /20	28MAY2012 /18	C	1	0	1	4	3
	Gastrointestinal disorders/ Vomiting/ VOMITING	17MAY2012 /20	Unknown/NA	I	6	1	1	3	1
	Investigations/ Blood creatinine increased/ HIGH LEVEL OF CREATININE	17MAY2012 /20	11JUN2012 /32	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0008/76 /M/W2/N	Nervous system disorders/ Encephalopathy/ ENCEPHALOPATHY	22MAY2012 /25	Unknown/NA	C	6	1	1	5	2
	Investigations/ Neutrophil count decreased/ LOW LEVEL OF ANC	17MAY2012 /20	28MAY2012 /18	C	1	0	1	4	3
	Investigations/ Blood urea increased/ HIGH LEVEL OF UREA	17MAY2012 /20	Unknown/NA	C	6	0	1	4	1
	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	27APR2012 /0	31MAY2012* /21	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0008/76 /M/W2/N	General disorders and administration site conditions/ Asthenia/ ASTHENIA	12JUN2012 /46	30JUL2012 /81	C	1	1	1	5 [PD]	3
	Investigations/ Blood albumin increased/ HIGH LEVEL OF ALBUMIN	12JUN2012 /46	Unknown/NA	C	6	0	1	5	1
	Nervous system disorders/ Encephalopathy/ ENCEPHALOPATHY	17MAY2012 /20	21MAY2012 /11	C	1	1	3 /17MAY2012 /Unknown	5	3
	General disorders and administration site conditions/ Asthenia/ ASTHENIA	07JUN2012 /41	11JUN2012 /32	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0008/76 /M/W2/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	27APR2012 /0	Unknown/NA	C	6	1	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ HYPOREXIA	12JUN2012 /46	Unknown/NA	C	6	0	1	5	2
	Investigations/ Blood albumin increased/ HIGH LEVEL OF ALBUMIN	28MAY2012 /31	11JUN2012 /32	C	1	0	1	5	2
	Investigations/ Blood creatinine increased/ CREATININE INCREASE	12JUN2012 /46	Unknown/NA	C	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0012/73 /F/W2/N	Investigations/ Haematocrit decreased/ LOW HCT	27DEC2012 /21	Unknown/NA	C	6	0	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ LEGS EDEMA	27DEC2012 /21	03JAN2013 /14	C	1	1	1	5	2
	Gastrointestinal disorders/ Ascites/ ASCITES	27DEC2012 /21	03JAN2013 /14	C	1	1	1	5	1
	Investigations/ Red blood cell count decreased/ LOW RBC	27DEC2012 /21	Unknown/NA	C	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0012/73 /F/W2/N	Investigations/ Blood glucose increased/ HIGH GLUCOSE LEVEL	27DEC2012 /21	Unknown/NA	C	6	0	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGHWITH PAINAT RIGHT LUNGBASIS	14DEC2012 /8	Unknown/NA	C	6	1	1	5	2
	Gastrointestinal disorders/ Upper gastrointestinal haemorrhage/ UPPER GASTROINTESTINAL BLEEDING (HEMATHESIS)	08JAN2013 /33	08JAN2013 /19	C	4	2	1	4 [PD]	5
	Investigations/ Blood albumin decreased/ LOW ALBUMIN LEVEL	27DEC2012 /21	Unknown/NA	C	6	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0012/73 /F/W2/N	Investigations/ Haemoglobin decreased/ LOW HGB	27DEC2012 /21	Unknown/NA	C	6	0	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	14DEC2012 /8	30DEC2012 /10	C	1	1	1	5	2
205-0015/71 /M/W2/N	Nervous system disorders/ Hepatic encephalopathy/ PORTAL SISTEMIC ENCEPHALOPATHY	09AUG2013 /51	03SEP2013 /32	I	1	1	2	4[Due To Hepatopathy ]	2
205-0016/70 /M/W2/Y	Investigations/ Neutrophil count decreased/ NEUTROPHYL COUNT DECREASE	11AUG2014 /412	21AUG2014 /-301	C	1	0	3 /13AUG2014 /26AUG2014	4[CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0016/70 /M/W2/Y	Gastrointestinal disorders/ Gingival disorder/ GINGIVAL INFLAMMATION	16JUL2013 /21	16JUL2013 /-702	C	1	2	1	5	1
205-0017/71 /M/W2/N	Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA OF THE HANDS	29AUG2013 /21	Unknown/NA	I	6	0	1	5 [CD]	1
205-0020/82 /M/W2/N	Gastrointestinal disorders/ Abdominal pain upper/ GASTRIC PAIN	12DEC2013 /62	Unknown/NA	C	6	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	23DEC2013 /73	Unknown/NA	C	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0022/67 /M/W2/Y	Gastrointestinal disorders/ Haematochezia/ BLOOD IN FECES	05NOV2013 /0	06NOV2013 /-6	C	1	0	1	5	
	Gastrointestinal disorders/ Oesophageal varices haemorrhage/ BLEEDING ESOPHAGEAL VARICES BY UPPER DIGESTIVE TRACT	22NOV2013 /17	22NOV2013 /10	C	4	0	2	5 [PD]	5
205-0024/80 /M/W2/N	Gastrointestinal disorders/ Faeces discoloured/ IPOCROMIC FECES	15FEB2014 /74	25FEB2014 /-10	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	28JAN2014 /56	04FEB2014 /-31	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0024/80 /M/W2/N	Skin and subcutaneous tissue disorders/ Rash/ CUTANEOUS RASH	13MAR2014 /100	Unknown/NA	C	6	1	1	5	1
	Renal and urinary disorders/ Chromaturia/ IPERCROMIC URINE	15FEB2014 /74	25FEB2014 /-10	C	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Rash/ CUTANEOUS RASH	15FEB2014 /74	25FEB2014 /-10	C	1	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	28JAN2014 /56	04FEB2014 /-31	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0025/63 /F/W2/Y	Skin and subcutaneous tissue disorders/ Rash/ NON-PRURITIC RASH ANKLES	11DEC2013 /12	16DEC2013 /-60	C	1	0	1	4	1
	Gastrointestinal disorders/ Ascites/ ASCITES	14FEB2014 /77	28FEB2014 /14	C	1	1	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	11DEC2013 /12	13DEC2013 /-63	C	1	1	1	5	1
207-0001/81 /F/W2/N	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING (UPPER LIMBS)	20MAR2012 /1	07JUN2012 /80	C	1	1	3 /26MAR2012 /Unknown	2	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0005/74 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	19JUN2012 /7	04JUL2012 /22	C	1	0	1	3	1
	Metabolism and nutrition disorders/ Hyperammonaemia/ HYPERAMMONIEMIA	19JUN2012 /7	04JUL2012 /22	C	1	1	1	3	1
207-0006/73 /M/W2/N	General disorders and administration site conditions/ Asthenia/ ASTHENIA	16JUL2012 /28	23JUL2012 /-42	C	1	0	1	5[Cancer Disease]	1
	Investigations/ Ammonia increased/ SERUM AMMONIUM LEVELS INCREASED	06AUG2012 /49	03OCT2012 /30	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0006/73 /M/W2/N	Psychiatric disorders/ Confusional state/ MENTAL CONFUSION	16JUL2012 /28	06AUG2012 /-28	C	1	0	1	5[Cancer Related]	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	06AUG2012 /49	03OCT2012 /30	C	1	0	1	5[General Conditions]	2
	Investigations/ Ammonia increased/ SERUM AMMONIUM LEVELS INCREASED	23JUL2012 /35	30SEP2012 /27	C	1	1	3 /03SEP2012 /Unknown	4[Related To Cancer]	3
	Nervous system disorders/ Tremor/ UPPER LIMB TREMOR	17JUL2012 /29	30JUL2012 /-35	C	1	0	1	5[General Conditions]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0006/73 /M/W2/N	Gastrointestinal disorders/ Haematochezia/ HEMATOCHEZIA	31JUL2012 /43	13AUG2012 /-21	C	1	0	1	4[Unknown]	1
	Nervous system disorders/ Syncope/ LYPOTIMIC AND SYNCOPAL EPISODES	26JUL2012 /38	06AUG2012 /-28	C	1	0	1	5[Cancer Related]	1
207-0008/66 /M/W2/N	Injury, poisoning and procedural complications/ Stoma site haemorrhage/ BLEEDING PERISTOMAL	14JUL2012 /5	15JUL2012 /-29	C	1	2	1	4[Patient Already Presented Ostomy At Screening]	2
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT LIVER NEOPLASM PROGRESSION	22AUG2012 /44	28AUG2012 /15	C	4		1	5[Worsening Of Clinical Conditions]	5

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0008/66 /M/W2/N	Injury, poisoning and procedural complications/ Post procedural haemorrhage/ BLEEDING OF ILEAL MUCOSIS (PATIENT WITH URETEROILEOSTOMY)	03AUG2012 /25	04AUG2012 /-9	C	1	2	1	4[Prensence Of Peristomal]	1
	Investigations/ Ammonia increased/ AMMONIUM INCREASED	13AUG2012 /35	28AUG2012 /15	C	1	0	1	5[Peristrom al Bleeding]	2
	Investigations/ Ammonia increased/ AMMONIUM INCREASED	31JUL2012 /22	12AUG2012 /-1	C	1	0	1	5[Hcc]	3
	General disorders and administration site conditions/ Asthenia/ ASTHENIA	06AUG2012 /28	28AUG2012 /15	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0011/78 /M/W2/N	Metabolism and nutrition disorders/ Hyperammonaemia/ HYPERAMMONIEMIA	24JAN2013 /3	06MAR2013 /44	C	1		1	5	
	Vascular disorders/ Peripheral venous disease/ VENOUS INSUFFICIENCY	21JAN2013 /0	06MAR2013 /44	C	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Pulmonary oedema/ LUNG EDEMA	24JAN2013 /3	06MAR2013 /44	C	1		2	5[Hepatic Cirrhosis Complicatio n]	3
207-0015/77 /M/W2/N	Gastrointestinal disorders/ Vomiting/ VOMITING	01SEP2013 /19	03SEP2013 /-49	C	1	1	1	4[CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0020/77 /M/W2/N	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	20AUG2014 /63	17SEP2014 /35	C	1	0	3 /20AUG2014 /Unknown	5 [PD]	3
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	20AUG2014 /63	17SEP2014 /35	C	1	0	3 /20AUG2014 /Unknown	5 [PD]	3
	Gastrointestinal disorders/ Rectal tenesmus/ RECTAL TENESMUS	31JUL2014 /43	17SEP2014 /35	C	1	0	1	5 [PD]	1
	Investigations/ Blood bilirubin increased/ INCREASED TOTAL BILIRUBIN	20AUG2014 /63	17SEP2014 /35	C	1	0	3 /20AUG2014 /Unknown	5 [PD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0020/77 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ LOWER LIMBS EDEMA	21AUG2014 /64	04SEP2014 /22	C	1	1	1	5	2
	General disorders and administration site conditions/ Asthenia/ ASTHENIA	07AUG2014 /50	28AUG2014 /15	C	1	0	1	5 [PD]	1
	General disorders and administration site conditions/ Oedema peripheral/ LOW LIMBS EDEMA	05SEP2014 /79	29SEP2014 /47	C	1	0	1	5	1
	General disorders and administration site conditions/ Asthenia/ HYPOASTHENIA	05JUL2014 /17	16JUL2014 /-28	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0020/77 /M/W2/N	General disorders and administration site conditions/ Asthenia/ ASTHENIA	28AUG2014 /71	17SEP2014 /35	C	1	0	1	5	3
	Psychiatric disorders/ Insomnia/ INSOMNIA	21AUG2014 /64	17SEP2014 /35	C	1	0	1	5 [PD]	1
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT DISEASE PROGRESSION	17SEP2014 /91	17SEP2014 /35	C	4	0	1	5	5
	Skin and subcutaneous tissue disorders/ Erythema/ ERITHEMA AT LOWER LIMBS	04JUL2014 /16	08JUL2014 /-36	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0020/77 /M/W2/N	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASE	25JUN2014 /7	23JUL2014 /-21	C	1	0	1	5	1
	General disorders and administration site conditions/ Asthenia/ ASTHENIA	30JUL2014 /42	05AUG2014 /-8	C	1	0	1	5	2
	Skin and subcutaneous tissue disorders/ Erythema/ ERYTHEMA AT LOWER LIMBS	23JUL2014 /35	05AUG2014 /-8	C	1	1	1	4	1
	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	20AUG2014 /63	17SEP2014 /35	C	1	0	3 /20AUG2014 /Unknown	5[PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0020/77 /M/W2/N	Skin and subcutaneous tissue disorders/ Erythema/ ERYTHEMA AT LOWER LIMBS	11JUL2014 /23	22JUL2014 /-22	C	1	1	1	4	1
	Metabolism and nutrition disorders/ Decreased appetite/ LACK OF APPETITE	21AUG2014 /64	17SEP2014 /35	C	1	0	1	5 [PD]	1
207-0021/74 /M/W2/N	General disorders and administration site conditions/ Asthenia/ ASTHENIA	29NOV2014 /163	11DEC2014 /-64	C	1	0	3 /28NOV2014 /12DEC2014	5	1
	General disorders and administration site conditions/ Oedema peripheral/ LOWER LIMBS EDEMA	10JUL2014 /21	27JUL2014 /-201	C	1	3	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0021/74 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ LOWER LIMBS EDEMA	27JUN2014 /8	10JUL2014 /-218	C	3	3	1	5	2
	Infections and infestations/ Lymphangitis/ LYMPHANGITIS	12DEC2014 /176	Unknown/NA	C	6	3	1	5	1
	General disorders and administration site conditions/ Asthenia/ WORSENING OF ASTHENIA	25JUL2014 /36	30JUL2014 /-198	C	1	0	1	5	2
	Investigations/ Alpha 1 foetoprotein increased/ ALPHA FETOPROTEIN INCREASE	02OCT2014 /105	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0021/74 /M/W2/N	Investigations/ Haemoglobin decreased/ HEMOGLOBIN DECREASE	28NOV2014 /162	12DEC2014 /-63	C	1	2	3 /28NOV2014 /12DEC2014	5	2
	Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	24FEB2015 /250	05MAR2015 /20	C	1	1	1	5[This Will Never Be Known.]	3
	Investigations/ Haemoglobin decreased/ HEMOGLOBIN DECREASE	24JUL2014 /35	07AUG2014 /-190	C	1	3	1	5	2
	Gastrointestinal disorders/ Ascites/ ASCITES	24FEB2015 /250	Unknown/NA	C	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0021/74 /M/W2/N	Infections and infestations/ Lymphangitis/ LYMPHANGITIS	27JUN2014 /8	11DEC2014 /-64	C	1	3	1	5	2
207-0022/74 /M/W2/N	General disorders and administration site conditions/ Pain/ GENERALIZED PAIN	24JUL2014 /14	27JUL2014 /-53	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hyperammonaemia/ HYPERAMMONEMIA	21JUL2014 /11	30JUL2014 /-50	C	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ BUTTOCK PAIN	21AUG2014 /42	25SEP2014 /7	C	1	0	1	1	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0022/74 /M/W2/N	Skin and subcutaneous tissue disorders/ Petechiae/ PETECHIAE IN THE LEGS	22AUG2014 /43	Unknown/NA	C	6	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	21AUG2014 /42	21AUG2014 /-28	C	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Muscle swelling/ SWELLING OF THE GLUTEUS	21AUG2014 /42	12SEP2014 /-6	C	1	0	1	1	1
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH	22JUL2014 /12	23JUL2014 /-57	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0022/74 /M/W2/N	Gastrointestinal disorders/ Abdominal hernia/ LAPAROCELE	22JUL2014 /12	Unknown/NA	C	6	0	1	5	1
	Investigations/ Blood potassium increased/ HIGH LEVEL OF POTASSIUM IN BLOOD	17JUL2014 /7	23JUL2014 /-57	C	1	1	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	21JUL2014 /11	02AUG2014 /-47	C	1	1	1	5[Hepatocar cinoma]	1
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT FOOT PAIN	28JUL2014 /18	02AUG2014 /-47	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0022/74 /M/W2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	18SEP2014 /70	18SEP2014 /0	C	1	0	1	2	1
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	21JUL2014 /11	30JUL2014 /-50	C	1	1	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	04SEP2014 /56	04SEP2014 /-14	C	1	0	1	2	1
	Investigations/ Blood uric acid increased/ HIGH LEVEL OF URIC ACID	17JUL2014 /7	08AUG2014 /-41	C	1	1	1	5	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0022/74 /M/W2/N	General disorders and administration site conditions/ Asthenia/ ASTHENIA	24JUL2014 /14	02AUG2014 /-47	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
208-0001/59 /M/W2/N	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	23APR2014 /580	23APR2014 /-440	I	1	0	1	5[Pre-Exist ing Condition With Intermittent Mild Arterial Blood Pressure Elevation]	3
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	12FEB2014 /510	12FEB2014 /-510	I	1	0	1	5[Pre-Exist ing Condition With Intermittent Mild Arterial Blood Pressure Elevation]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	23OCT2013 /398	23OCT2013 /-622	I	1	0	1	5[Pre-Exist ing Condition With Intermittent Mild Arterial Blood Pressure Elevation]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
208-0001/59 /M/W2/N	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	20JUN2013 /273	10SEP2013 /-665	I	6	0	1	5[Pre-Exist ing Condition With Intermittent Mild Arterial Blood Pressure Elevation]	2
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	07FEB2013 /140	08APR2013 /-820	I	6	0	1	5[Pre-Exist ing Condition With Intermittent Mild Arterial Blood Pressure Elevation]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	31OCT2012 /41	05FEB2013 /-882	I	6	0	1	5[Pre-Exist ing Condition With Intermittent Mild Arterial Blood Pressure Elevation]	2
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	03JAN2014 /470	11FEB2014 /-511	I	6	0	1	5[Pre-Exist ing Condition With Intermittent Mild Arterial Blood Pressure Elevation]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
208-0001/59 /M/W2/N	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	13FEB2014 /511	22APR2014 /-441	I	6	0	1	5[Pre-Exist ing Condition With Intermittent Mild Arterial Blood Pressure Elevation]	2
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	24OCT2013 /399	01JAN2014 /-552	I	6	0	1	5[Pre-Exist ing Condition With Intermittent Mild Arterial Blood Pressure Elevation]	2
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	27MAY2015 /979	02JUN2015 /-35	I	1	0	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	09APR2013 /201	09APR2013 /-819	I	1	1	1	5[Pre-Exist ing Condition With Intermittent Mild Arterial Blood Pressure Elevation]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
208-0001/59 /M/W2/N	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	03JAN2015 /835	10FEB2015 /-147	I	6	0	1	5	2
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	11SEP2013 /356	11SEP2013 /-664	I	1	0	1	5[Pre-Exist ing Condition With Intermitt t Mild Arterial Blood Pressure Elevation]	3
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	19JUN2013 /272	19JUN2013 /-748	I	1	0	1	5[Pre-Exist ing Condition With Intermitt t Mild Arterial Blood Pressure Elevation]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
	Musculoskeletal and connective tissue disorders/ Back pain/ LEFT LUMBAR PAIN	20JUN2014 /638	02JUL2014 /-370	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
208-0001/59 /M/W2/N	Nervous system disorders/ Somnolence/ SOMNOLENCE	20JUN2014 /638	02JUL2014 /-370	I	1	0	1	5	1
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	12SEP2013 /357	22OCT2013 /-623	I	6	0	1	5[Pre-Exist ing Condition With Intermitt t Mild Arterial Blood Pressure Elevation]	2
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	12NOV2014 /783	18NOV2014 /-231	I	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	01MAY2014 /588	30SEP2014 /-280	I	6	0	1	5[Pre-Exist ing Condition With Intermittent Mild Arterial Blood Pressure Elevation]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
208-0001/59 /M/W2/N	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	02JAN2014 /469	02JAN2014 /-551	I	1	0	1	5[Pre-Exist ing Condition With Intermittent Mild Arterial Blood Pressure Elevation]	3
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	02OCT2014 /742	21OCT2014 /-259	I	6	0	1	5	2
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	01OCT2014 /741	01OCT2014 /-279	I	1	0	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	24APR2014 /581	29APR2014 /-434	I	6	0	1	5[Pre-Exist ing Condition With Intermittent Mild Arterial Blood Pressure Elevation]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
208-0001/59 /M/W2/N	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	10APR2013 /202	18JUN2013 /-749	I	6	0	1	5[Pre-Exist ing Condition With Intermittent Mild Arterial Blood Pressure Elevation]	2
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	30APR2014 /587	30APR2014 /-433	I	1	0	1	5[Pre-Exist ing Condition With Intermittent Mild Arterial Blood Pressure Elevation]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	06FEB2013 /139	06FEB2013 /-881	I	1	0	1	5[Pre-Exist ing Condition With Intermittent Mild Arterial Blood Pressure Elevation]	3
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	20NOV2014 /791	16DEC2014 /-203	I	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
208-0001/59 /M/W2/N	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	11FEB2015 /874	17FEB2015 /-140	I	1	0	1	5	3
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	17DEC2014 /818	02JAN2015 /-186	I	1	0	1	5	3
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	19NOV2014 /790	19NOV2014 /-230	I	1	0	1	5	3
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	22OCT2014 /762	11NOV2014 /-238	I	1	0	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
208-0002/82 /F/W2/N	Gastrointestinal disorders/ Vomiting/ BILIARY VOMITING	04OCT2012 /14	04OCT2012 /-43	I	1	0	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	15OCT2012 /25	16OCT2012 /-31	I	1	0	1	3	1
	Gastrointestinal disorders/ Vomiting/ BILIARY VOMITING	15OCT2012 /25	16OCT2012 /-31	I	1	1	1	4	1
208-0006/69 /F/W2/N	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	16OCT2013 /49	29OCT2013 /-29	I	1	0	1	5 [CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
208-0006/69 /F/W2/N	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	13NOV2013 /77	Unknown/NA	I	6	0	1	5[Present Also Before Taking Ip, So Not Related.]	1
208-0007/53 /M/W2/N	Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLICEMIA	16JUL2014 /9	29JUL2014 /-64	C	2	0	1	5	3
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	08JUL2014 /1	16JUL2014 /-77	I	1	1	1	5	1
	Metabolism and nutrition disorders/ Type 2 diabetes mellitus/ DIABETES MELLITUS TYPE 2	30JUL2014 /23	Unknown/NA	C	6	0	1	5	

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
209-0001/66 /M/W2/Y	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	28FEB2013 /105	Unknown/NA	I	6	0	1	5 [PD]	2
	Gastrointestinal disorders/ Abdominal pain upper/ STOMACH ACHE	22NOV2012 /7	06DEC2012 /-56	C	1	0	1	5	1
	Hepatobiliary disorders/ Portal vein thrombosis/ NEOPLASTIC PORTAL VEIN THROMBOSIS	31JAN2013 /77	18APR2013 /77	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ DECREASE OF APPETITE	22NOV2012 /7	06DEC2012 /-56	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
209-0001/66 /M/W2/Y	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	13DEC2012 /28	24JAN2013 /-7	I	1	1	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	28FEB2013 /105	Unknown/NA	I	6	1	1	5 [PD]	1
	General disorders and administration site conditions/ Asthenia/ ASTHENIA	16JAN2013 /62	24JAN2013 /-7	C	1	1	1	5	2
	Nervous system disorders/ Head discomfort/ SENSATION OF HEAD HEAVINESS	22NOV2012 /7	06DEC2012 /-56	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
209-0001/66 /M/W2/Y	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	17JAN2013 /63	24JAN2013 /-7	C	1	1	1	4	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	29DEC2012 /44	02JAN2013 /-29	I	1	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	16JAN2013 /62	16JAN2013 /-15	I	1	0	1	5	1
	General disorders and administration site conditions/ Asthenia/ ASTHENIA	28FEB2013 /105	Unknown/NA	C	6	1	1	5 [PD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
209-0004/74 /M/W2/N	Renal and urinary disorders/ Micturition urgency/ INCREASED URINARY URGENCY	01JUN2013* /53	26OCT2013 /123	I	1	1	1	5	1
209-0008/66 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ PERIPHERAL EDEMA	10SEP2013 /61	Unknown/NA	C	6	1	1	4	2
	Gastrointestinal disorders/ Ascites/ ASCITIS	24SEP2013 /75	31OCT2013* /37	C	1	1	1	4	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	01SEP2013* /52	20SEP2013 /-4	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
209-0008/66 /M/W2/N	Psychiatric disorders/ Anxiety/ ANXIETY	01AUG2013 /21	Unknown/NA	I	6	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	27SEP2013 /78	Unknown/NA	C	6	1	1	5	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	27SEP2013 /78	Unknown/NA	I	6	1	1	5	3
	Gastrointestinal disorders/ Ascites/ ASCITIS	01OCT2013* /82	Unknown/NA	C	6	2	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
209-0008/66 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	27SEP2013 /78	Unknown/NA	I	6	1	1	5	2
	Skin and subcutaneous tissue disorders/ Skin lesion/ CUTANEOUS PRURIGINOUS LESION OF THE LOWER LIMB	15AUG2013 /35	Unknown/NA	I	6	0	1	4	1
209-0012/63 /M/W2/N	Vascular disorders/ Hypertension/ HYPERTENSION	18DEC2013 /15	Unknown/NA	I	6	1	1	4	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	23FEB2014 /82	25FEB2014 /-79	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
210-0001/67 /M/W2/N	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING	31OCT2013 /62	13MAR2014 /28	C	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA IN THE LOWER LIMBS	31OCT2013 /62	12DEC2013 /-63	C	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Joint swelling/ ANKLES SWELLING	04OCT2013 /35	21NOV2013 /-84	I	1	0	1	2	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	03DEC2013 /95	04DEC2013 /-71	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
210-0001/67 /M/W2/N	Infections and infestations/ Gastroenteritis viral/ VIRAL GASTROENTERITIS	27DEC2013 /119	27DEC2013 /-48	C	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	20FEB2014 /174	06MAR2014 /21	C	1	1	1	5 [PD]	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	02SEP2013 /3	05DEC2013 /-70	C	1	0	1	5	1
210-0002/80 /M/W2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	25MAR2014 /167	27MAR2014 /-153	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
210-0002/80 /M/W2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	22OCT2013 /13	22OCT2013 /-309	C	1	0	1	5[Just 1 Episode]	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	25MAR2014 /167	27MAR2014 /-153	C	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCH	30APR2014 /203	29MAY2014 /-90	C	1	1	1	2	1
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCH	09APR2014 /182	29APR2014 /-120	C	2	1	1	2	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
210-0007/73 /M/W2/N	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	21MAY2015 /318	26MAY2015 /-42	C	1	2	3 /21MAY2015 /04JUN2015	5	3
210-0011/73 /M/W2/Y	General disorders and administration site conditions/ Asthenia/ ASTHENIA	14DEC2014 /27	21DEC2014 /-45	C	1	0	1	5[Fatigue Due To Indigestion ]	1
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT DISEASE PROGRESSION	04MAR2015 /107	04MAR2015 /28	C	4	0	1	5[PD]	5
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	14DEC2014 /27	16DEC2014 /-50	C	3	2	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
210-0011/73 /M/W2/Y	Gastrointestinal disorders/ Dyspepsia/ INDIGESTION	12DEC2014 /25	12DEC2014 /-54	C	1	1	1	5	1
251-0001/55 /F/W2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	21AUG2012 /21	Unknown/NA	I	6	1	1	4	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	13NOV2012 /105	Unknown/NA	C	6	0	1	3	2
	Blood and lymphatic system disorders/ Anaemia/ ANAEMIA	01NOV2012* /93	Unknown/NA	C	6	2	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
251-0001/55 /F/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	02NOV2012 /94	12NOV2012 /6	C	3	1	1	3	1
	Musculoskeletal and connective tissue disorders/ Back pain/ INCREASED BACK PAIN	02NOV2012 /94	Unknown/NA	C	6	1	1	4	2
	Investigations/ Blood alkaline phosphatase increased/ RAISED ALK PHOS	02OCT2012 /63	17OCT2012 /-20	C	1	0	1	3	1
	Investigations/ Blood alkaline phosphatase increased/ RAISED ALK PHOS	21AUG2012 /21	18SEP2012 /-49	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
251-0001/55 /F/W2/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	19OCT2012 /80	23OCT2012 /-14	I	1	0	3 /23OCT2012 /30OCT2012	4	2
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	01SEP2012 /32	18OCT2012 /-19	I	3	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	18SEP2012 /49	Unknown/NA	I	6	0	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	04SEP2012 /35	18SEP2012 /-49	C	1	0	3 /04SEP2012 /11SEP2012	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
251-0001/55 /F/W2/N	Investigations/ Weight decreased/ WEIGHTLOSS	18SEP2012 /49	Unknown/NA	C	6	2	1	3	2
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	28OCT2012 /89	03DEC2012 /27	C	3	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	24OCT2012 /85	27OCT2012 /-10	C	1	1	1	4 [CD]	4
	General disorders and administration site conditions/ Fatigue/ FATIGUE	08AUG2012 /8	08AUG2012 /-90	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
251-0001/55 /F/W2/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	04DEC2012 /126	Unknown/NA	C	6	1	2	4	3
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	31AUG2012 /31	24SEP2012 /-43	C	1	0	1	4	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	21AUG2012 /21	Unknown/NA	I	6	1	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	29AUG2012 /29	31AUG2012 /-67	C	1	2	1	4 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
251-0001/55 /F/W2/N	Musculoskeletal and connective tissue disorders/ Back pain/ BACK ACHE	07AUG2012 /7	13AUG2012 /-85	C	1	1	1	3	2
	Respiratory, thoracic and mediastinal disorders/ Hypoxia/ HYPOXIA	19NOV2012 /111	26DEC2012 /50	C	1	2	2	4 [PD]	3
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK ACHE	14AUG2012 /14	01NOV2012 /-5	C	1	1	1	3	1
252-0002/76 /M/W2/N	Musculoskeletal and connective tissue disorders/ Joint swelling/ ANKLE SWELLING	10SEP2012 /13	29SEP2012 /25	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0002/76 /M/W2/N	Musculoskeletal and connective tissue disorders/ Muscular weakness/ BILATERAL LEG WEAKNESS	09SEP2012 /12	16SEP2012 /12	C	1	1	1	3	3
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	05SEP2012 /8	16SEP2012 /12	I	1	1	1	2	2
	Musculoskeletal and connective tissue disorders/ Muscular weakness/ ARM WEAKNESS	17SEP2012 /20	29SEP2012 /25	I	1	0	1	3	1
	Skin and subcutaneous tissue disorders/ Rash/ RASH ON LEGS	18SEP2012 /21	20SEP2012 /16	C	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0002/76 /M/W2/N	Musculoskeletal and connective tissue disorders/ Muscular weakness/ BILATERAL ARM WEAKNESS	09SEP2012 /12	16SEP2012 /12	C	1	1	1	3	3
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	17SEP2012 /20	Unknown/NA	I	6	1	1	2	1
	Skin and subcutaneous tissue disorders/ Rash macular/ ERYTHRO MACULAR RASH ON LEGS AND BUTTOCKS	09SEP2012 /12	17SEP2012 /13	C	1	1	2	1	3
	Nervous system disorders/ Dysgeusia/ METALLIC TASTE	07SEP2012 /10	Unknown/NA	C	5	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0002/76 /M/W2/N	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	07SEP2012 /10	Unknown/NA	C	6	1	1	3	2
	Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT ACHES	07SEP2012 /10	16SEP2012 /12	C	1	1	1	2	2
	Musculoskeletal and connective tissue disorders/ Arthralgia/ ACHING JOINTS	17SEP2012 /20	20SEP2012 /16	C	1	1	1	3	1
	Musculoskeletal and connective tissue disorders/ Muscular weakness/ LEG WEAKNESS	17SEP2012 /20	29SEP2012 /25	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0003/68 /M/W2/N	Nervous system disorders/ Lethargy/ LETHARGY	24JAN2013 /24	Unknown/NA	C	6	0	1	5	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	24MAR2013 /83	Unknown/NA	C	6	1	1	3	2
	Nervous system disorders/ Lethargy/ LETHARGY	11JAN2013 /11	23JAN2013 /-55	C	1	0	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	05JAN2013 /5	10JAN2013 /-68	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0003/68 /M/W2/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	22MAR2013 /81	Unknown/NA	C	6	1	1	3	2
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	11FEB2013 /42	21MAR2013 /2	C	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal pain lower/ INTERMITTENT LOWER ABDOMINAL PAIN	09FEB2013 /40	23MAR2013 /4	I	3	1	1	3	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	23MAR2013 /82	24MAR2013 /5	C	1	1	1	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0003/68 /M/W2/N	Gastrointestinal disorders/ Abdominal pain upper/ LEFT UPPER QUADRANT PAIN	10JAN2013 /10	18FEB2013 /-29	C	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Back pain/ LOWER BACK PAIN	09FEB2013 /40	Unknown/NA	C	6	1	1	3	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	09JAN2013 /9	10JAN2013 /-68	C	1	0	1	2	1
	Gastrointestinal disorders/ Proctalgia/ INTERMITTENT BURNING ANAL PAIN	09FEB2013 /40	Unknown/NA	I	6	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0003/68 /M/W2/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	25JAN2013 /25	27JAN2013 /-51	C	1	1	1	3	2
	Injury, poisoning and procedural complications/ Fall/ COLLAPSE (COLLAPSED ON TOILET FLOOR, UNSURE OF CAUSE)	24MAR2013 /83	24MAR2013 /5	C	1	0	1	5	2
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	31DEC2012 /0	04FEB2013 /-43	C	1	0	1	2	1
	Skin and subcutaneous tissue disorders/ Miliaria/ HEAT LUMPS RIGHT BUTTOCK	11JAN2013 /11	22JAN2013 /-56	I	1	0	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0011/81 /M/BL/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	28MAY2015 /184	Unknown/NA	C	6	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ SHOULDER MYALGIA	28NOV2014 /3	08DEC2014 /-211	C	3	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ RIB PAIN	06JUN2015 /193	06JUN2015 /-31	I	1	0	1	4	1
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	17MAY2015 /173	20MAY2015 /-48	I	1	0	1	4 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0011/81 /M/BL/N	Musculoskeletal and connective tissue disorders/ Muscle spasms/ LEG CRAMPS	21APR2015 /147	Unknown/NA	I	6	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ RIGHT PARASPINAL MUSCLE PAIN	11FEB2015 /78	12FEB2015 /-145	C	1	0	1	4	1
	General disorders and administration site conditions/ Asthenia/ ASTHENIA	28NOV2014 /3	08DEC2014 /-211	I	1	0	1	3	1
	Vascular disorders/ Hypertension/ HYPERTENSION	02DEC2014 /7	23DEC2014 /-196	I	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0011/81 /M/BL/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	31MAR2015 /126	Unknown/NA	I	6	0	1	4	1
	General disorders and administration site conditions/ Non-cardiac chest pain/ NON-CARDIAC LEFT SIDED CHEST PAIN	23APR2015 /149	23APR2015 /-75	I	1	0	1	4	1
	Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	24MAY2015 /180	Unknown/NA	I	6	0	1	4 [CD]	1
253-0002/63 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	25MAY2012 /77	Unknown/NA	C	6	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0002/63 /M/W2/N	Musculoskeletal and connective tissue disorders/ Limb discomfort/ LEG DISCOMFORT	09MAY2012 /61	11MAY2012 /7	C	1	0	1	4	1
	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT PAIN	18MAY2012 /70	25MAY2012 /21	I	1	1	1	4	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	05MAY2012 /57	25MAY2012 /21	I	1	1	1	4	1
	Infections and infestations/ Lower respiratory tract infection/ CHEST INFECTION	18MAY2012 /70	25MAY2012 /21		1		1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0002/63 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	04MAY2012 /56	11MAY2012 /7	C	1	0	1	3	2
	General disorders and administration site conditions/ Injection site pain/ LEFT ARM INJECTION SITE PAIN	11MAY2012 /63	25MAY2012 /21	I	1	0	1	1	1
	General disorders and administration site conditions/ Injection site erythema/ REDNESS INJECTION SITE	30MAR2012 /21	13APR2012 /-21	C	1	0	1	2	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	11MAY2012 /63	25MAY2012 /21	C	1	0	2	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0002/63 /M/W2/N	General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN (LEFT ARM)	09MAR2012 /0	09MAR2012 /-56	I	1	0	1	1	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	09MAY2012 /61	25MAY2012 /21	I	1	0	1	4	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	02MAY2012 /54	02MAY2012 /-2	I	1	1	1	4	1
	Metabolism and nutrition disorders/ Hypoglycaemia/ HYPOGLYCAEMIA	18APR2012 /40	18APR2012 /-16	I	1	2	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0002/63 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LEG OEDEMA	23MAY2012 /75	09AUG2012 /97	C	5	0	1	4	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	11MAR2012 /2	12MAR2012 /-53	I	1	1	1	3	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	04APR2012 /26	10APR2012 /-24	C	1	0	3 /05APR2012 /13APR2012	3	3
	General disorders and administration site conditions/ Injection site rash/ RASH INJECTION SITE	30MAR2012 /21	13APR2012 /-21	C	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0002/63 /M/W2/N	Metabolism and nutrition disorders/ Decreased appetite/ APETITE (LOSS)	01APR2012 /23	10APR2012 /-24	C	1	0	1	4	1
	General disorders and administration site conditions/ Injection site rash/ RASH AT INJECTION SITE	27APR2012 /49	04MAY2012 /0	C	1	1	1	2	1
	General disorders and administration site conditions/ Influenza like illness/ FLU LIKE SYMPTOMS	18MAY2012 /70	25MAY2012 /21	C	1	0	1	4	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	03APR2012 /25	10APR2012 /-24	I	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0002/63 /M/W2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	25MAR2012 /16	03APR2012 /-31	I	1	0	1	3	1
	Metabolism and nutrition disorders/ Decreased appetite/ LOW APETITE	04MAY2012 /56	25MAY2012 /21	C	1	0	1	4	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	18MAR2012 /9	19MAR2012 /-46	I	1	1	1	3	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	04MAY2012 /56	25MAY2012 /21	I	1	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0002/63 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Epistaxis/ NOSEBLEED	02MAY2012 /54	Unknown/NA	I	5	0	1	4	1
	Investigations/ Blood creatinine increased/ ELEVATED CREATININE	30MAR2012 /21	18MAY2012 /14	C	1	1	1	4	2
	Musculoskeletal and connective tissue disorders/ Joint swelling/ SWOLLEN ANKLES	23MAY2012 /75	Unknown/NA	C	5		1	4	1
253-0010/76 /M/W2/N	Blood and lymphatic system disorders/ Anaemia/ ANAEMIA	23AUG2013 /77	06SEP2013 /-63	C	1	2	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0010/76 /M/W2/N	Musculoskeletal and connective tissue disorders/ Muscular weakness/ MUSCLE WEAKNESS	23AUG2013 /77	Unknown/NA	C	6	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	06DEC2013 /182	Unknown/NA	I	5	0	1	4	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	28JUN2013 /21	Unknown/NA	I	6	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Joint swelling/ SWOLLEN ANKLES	16AUG2013 /70	Unknown/NA	C	6	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0010/76 /M/W2/N	Musculoskeletal and connective tissue disorders/ Muscle spasms/ LEG CRAMPS	01SEP2013* /86	Unknown/NA	I	6	1	1	4	1
	Gastrointestinal disorders/ Abdominal distension/ SWOLLEN ABDOMEN	16AUG2013 /70	Unknown/NA	C	6	1	1	4	2
	Investigations/ Neutrophil count decreased/ DECREASED NEUTROPHIL COUNT	12JUL2013 /35	26JUL2013 /-105	C	1	0	3 /19JUL2013 /02AUG2013	4	3
	Gastrointestinal disorders/ Stomatitis/ STOMATITIS	18OCT2013 /133	Unknown/NA	C	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0010/76 /M/W2/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	05JUL2013 /28	Unknown/NA	I	6	1	1	4	1
	Gastrointestinal disorders/ Abdominal distension/ DISTENDED ABDOMEN	28JUN2013 /21	12JUL2013 /-119	C	1	1	1	4	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	18OCT2013 /133	Unknown/NA	I	6	1	1	4	1
	Injury, poisoning and procedural complications/ Excoriation/ EXCORIATING RASH ARMS AND LEGS	18OCT2013 /133	06DEC2013 /28	I	1	2	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0010/76 /M/W2/N	Gastrointestinal disorders/ Ascites/ ASCITES ON CLINICAL EXAMINATION	18OCT2013 /133	01NOV2013 /-7	C	1	0	1	4	1
	Investigations/ Blood glucose increased/ RAISED BLOOD GLUCOSE	20SEP2013 /105	Unknown/NA	C	6	0	1	4	2
254-0001/69 /M/W2/N	Gastrointestinal disorders/ Ascites/ ASCITES	12AUG2012 /86	Unknown/NA	C	6	0	1	5	1
	Nervous system disorders/ Dizziness/ DIZZINESS	24MAY2012 /6	24MAY2012 /-82	C	3	2	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
254-0001/69 /M/W2/N	Musculoskeletal and connective tissue disorders/ Spinal pain/ OCCASSIONAL SHARP PAIN IN UPPER THORACIC SPINE ON ARM EXTENSION	23JUL2012 /66	Unknown/NA	I	6	1	1	5	1
	General disorders and administration site conditions/ Injection site erythema/ MILD SKIN REACTION POST INJECTION (REDNESS ON INJECTION SITE)	19JUN2012 /32	20JUN2012 /-55	C	1	0	1	1	1
	Musculoskeletal and connective tissue disorders/ Joint swelling/ SWOLLEN ANKLES	07JUL2012 /50	27JUL2012 /-18	I	1	0	1	5	1
	Infections and infestations/ Urinary tract infection/ POSSIBLE UTI	06JUL2012 /49	13JUL2012 /-32	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
254-0001/69 /M/W2/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN, WORSENER	06JUL2012 /49	16JUL2012 /-29	I	1	1	1	4	3
	Injury, poisoning and procedural complications/ Lower limb fracture/ LEFT LEG FRACTURE - WEBER B FRACTURE OF LEFT LATERAL MALLEOUS (LEFT ANKLE)AND DISTAL FIBULA.	24MAY2012 /6	13JUL2012 /-32	C	1	2	1	5[Not Related To Study Drug. Aetiology Unknown.]	3
257-0001/47 /M/A4/Y	Nervous system disorders/ Spinal cord compression/ SPINAL CORD COMPRESSION	12APR2012 /7	10SEP2012 /109	C	3	3	3 /12APR2012 /26APR2012	5[CD]	3
	Injury, poisoning and procedural complications/ Wound complication/ WOUND COMPLICATION	24MAY2012 /49	10SEP2012 /109	C	3	2	2	5[CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0002/56 /M/W2/N	General disorders and administration site conditions/ Peripheral swelling/ RIGHT UPPER ARM SWELLING	28APR2012 /9	10MAY2012 /-7	C	1	0	1	5	1
	General disorders and administration site conditions/ Injection site pain/ PAIN AT MEDICATION INJECTION SITE	27APR2012 /8	10MAY2012 /-7	C	1	1	1	2	2
	Skin and subcutaneous tissue disorders/ Pruritus generalised/ PRURITUS (BODY)	27APR2012 /8	Unknown/NA	C	6	1	1	2	1
	Skin and subcutaneous tissue disorders/ Rash/ RASH (TRUNK, LEGS, ARMS)	27APR2012 /8	10MAY2012 /-7	C	1	1	3 /03MAY2012 /17MAY2012	2	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0002/56 /M/W2/N	Immune system disorders/ Anaphylactic reaction/ ANAPHYLACTIC REACTION	17MAY2012 /28	20MAY2012 /3	I	1	1	2	1	3
257-0007/80 /M/W2/N	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ PAIN ON RIGHT SHOULDER	05MAY2013 /73	Unknown/NA	I	6	0	1	4[CD]	2
	Skin and subcutaneous tissue disorders/ Rash/ RASH	15MAR2013 /22	03APR2013 /-36	C	1	1	1	3	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	08MAR2013 /15	Unknown/NA	I	6	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0007/80 /M/W2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	08MAR2013 /15	20APR2013 /-19	I	1	0	1	2	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	08MAR2013 /15	Unknown/NA	C	6	0	1	2	2
	Infections and infestations/ Lower respiratory tract infection/ LOWER RESPIRATORY TRACT INFECTION	08MAR2013 /15	21MAR2013 /-49	C	1	1	1	5	2
	Infections and infestations/ Viral upper respiratory tract infection/ UPPER RESPIRATORY TRACT VIRAL INFECTION	25FEB2013 /4	07MAR2013 /-63	C	1	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0007/80 /M/W2/N	General disorders and administration site conditions/ Injection site pain/ PAIN (INJECTION SITE)	09MAY2013 /77	Unknown/NA	C	6	0	1	1	2
	Skin and subcutaneous tissue disorders/ Rash maculo-papular/ MACULOPAPULAR RASH ON TRUNK AND PELVIS	02MAY2013 /70	Unknown/NA	C	6	1	1	3	1
	General disorders and administration site conditions/ Injection site erythema/ ERYTHEMA AROUND INJECTION SITE	25APR2013 /63	Unknown/NA	C	6	0	1	1	1
	General disorders and administration site conditions/ Injection site pain/ PAIN IN INJECTION SITE	25APR2013 /63	08MAY2013 /-1	C	1	0	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0008/80 /F/W2/N	Musculoskeletal and connective tissue disorders/ Spinal pain/ PAINFUL LEFT SPINE RADIATING TO LEFT ARM	04APR2013 /7	Unknown/NA	C	5	0	1	5	1
	Immune system disorders/ Hypersensitivity/ ALLERGIC REACTION	30APR2013 /33	08MAY2013 /-36	C	1	1	3 /02MAY2013 /09MAY2013	1	2
	Immune system disorders/ Hypersensitivity/ ALLERGIC REACTION	04APR2013 /7	21APR2013 /-53	C	1	0	3 /11APR2013 /25APR2013	1	2
	General disorders and administration site conditions/ Injection site rash/ RASH - INJECTION SITE	05APR2013 /8	15MAY2013 /-29	C	1	1	3 /11APR2013 /25APR2013	1	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0010/42 /M/BL/Y	Gastrointestinal disorders/ Constipation/ CONSTIPATION	01AUG2013 /70	Unknown/NA	I	6	0	1	4	1
	Gastrointestinal disorders/ Haemorrhoids/ HEMHORROIDS	01AUG2013 /70	Unknown/NA	I	6	0	1	4	1
	Investigations/ Cardiac murmur/ SOFT EJECTION SYSTOLIC MURMOUR AT THE LEFT STERNAL EDGE	23MAY2013 /0	30MAY2013 /-67	C	1	0	1	4	1
257-0012/76 /M/W2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	10JUN2013 /28	Unknown/NA	C	6	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0012/76 /M/W2/N	Infections and infestations/ Sepsis/ SEPSIS	20JUN2013 /38	25JUN2013 /18	C	4	1	2	4 [CD]	4
	Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION WITH FAST VENTRICULAR RATE	20JUN2013 /38	25JUN2013 /18	C	1	0	1	5 [CD]	3
	Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	01JUN2013 /19	Unknown/NA	C	6	1	1	5	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	30MAY2013 /17	01JUN2013 /-6	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0012/76 /M/W2/N	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL BLOATING	16MAY2013 /3	01JUN2013 /-6	I	1	0	1	5	1
	Gastrointestinal disorders/ Flatulence/ FLATUS	16MAY2013 /3	23MAY2013 /-15	I	1	0	1	5	1
	General disorders and administration site conditions/ Suprapubic pain/ SUPRAPUBIC PAIN	08JUN2013 /26	11JUN2013 /4	C	1	0	1	5[Spontaneo us]	1
	Nervous system disorders/ Lethargy/ LETHARGY	11JUN2013 /29	Unknown/NA	C	6	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0012/76 /M/W2/N	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	10JUN2013 /28	Unknown/NA	C	6	0	1	3	1
257-0015/69 /F/BL/Y	General disorders and administration site conditions/ Fatigue/ FATIGUE	24APR2014 /10	Unknown/NA	C	6	0	1	4	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	24APR2014 /10	Unknown/NA	C	6	0	1	4	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	24APR2014 /10	Unknown/NA	C	6	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0015/69 /F/BL/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	24APR2014 /10	Unknown/NA	C	6	0	1	4	2
	Musculoskeletal and connective tissue disorders/ Arthritis/ ARTHRITIS	27APR2014 /13	08MAY2014 /24	C	1	1	1	4 [PD]	3
	General disorders and administration site conditions/ Injection site pain/ PAIN (RIGHT BUTTOCK INJECTION SITE)	24APR2014 /10	25APR2014 /11	C	1	0	2	1	3
	Hepatobiliary disorders/ Jaundice/ JAUNDICE	24APR2014 /10	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0015/69 /F/BL/Y	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	24APR2014 /10	Unknown/NA	C	6	0	1	5	1
	Gastrointestinal disorders/ Ascites/ ASCITES	24APR2014 /10	Unknown/NA	C	6	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ PAIN (RIGHT HIP)	24APR2014 /10	25APR2014 /11	C	1	0	1	1	3
257-0017/74 /M/A8/Y	Vascular disorders/ Hypertension/ UNCONTROLLED HIGH BLOOD PRESSURE	16JUN2014 /45	19JUN2014 /-32	C	1	1	3 /16JUN2014 /23JUN2014	5[CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0017/74 /M/A8/Y	Skin and subcutaneous tissue disorders/ Rash macular/ ERYMATOUS MACULAR RASH (LOWER LIMBS)	02JUN2014 /31	09JUN2014 /-42	C	1	1	1	2	1
	Nervous system disorders/ Headache/ FRONTAL HEADACHES	19MAY2014 /17	09JUN2014 /-42	I	1	0	1	5	1
	General disorders and administration site conditions/ Oedema/ BILATRAL PITTING OEDEMA	12MAY2014 /10	19MAY2014 /-63	C	1	0	1	5	1
	Nervous system disorders/ Dizziness/ INCREASING DIZZINESS	12MAY2014 /10	19MAY2014 /-63	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0017/74 /M/A8/Y	Skin and subcutaneous tissue disorders/ Purpura/ PURPURIC AREA OVER THE HANDS	21JUL2014 /80	Unknown/NA	C	6	0	1	5	1
	Gastrointestinal disorders/ Toothache/ TOOTHACHE	14JUL2014 /73	18JUL2014 /-3	C	1	0	3 /14JUL2014 /21JUL2014	5	1
	Nervous system disorders/ Lacunar infarction/ SMALL LEFT INTERNAL CAPSULAR LACUNAR INFARCT	16JUN2014 /45	19JUN2014 /-32	C	3	1	1	5 [CD]	3
	General disorders and administration site conditions/ Injection site bruising/ BRUISING ON RIGHT ARM (INJECTION SITE)	23JUN2014 /52	07JUL2014 /-14	C	1	0	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0017/74 /M/A8/Y	General disorders and administration site conditions/ Fatigue/ FATIGUE	16JUN2014 /45	Unknown/NA	C	6	0	1	5	2
257-0018/53 /M/A6/N	Gastrointestinal disorders/ Nausea/ NAUSEA	07MAY2014 /9	18MAY2014 /16	C	1	0	1	5	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	07MAY2014 /9	Unknown/NA	C	6	0	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	07MAY2014 /9	Unknown/NA	C	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0018/53 /M/A6/N	General disorders and administration site conditions/ Fatigue/ WORSENING OF FATIGUE	12MAY2014 /14	Unknown/NA	C	6	0	1	5	2
	Hepatobiliary disorders/ Jaundice/ INCREASING JAUNDICE	19MAY2014 /21	22MAY2014 /20	C	1	0	2	5 [PD]	3
	Gastrointestinal disorders/ Nausea/ NAUSEA	19MAY2014 /21	Unknown/NA	C	6	1	1	5	2
	Hepatobiliary disorders/ Jaundice/ JAUNDICE	12MAY2014 /14	19MAY2014 /17	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0018/53 /M/A6/N	Renal and urinary disorders/ Acute kidney injury/ ACUTE RENAL FAILURE	12MAY2014 /14	Unknown/NA	C	6	0	1	5	1
	Investigations/ Haemoglobin decreased/ LOW HAEMOGLOBIN	12MAY2014 /14	Unknown/NA	C	6	2	1	5	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	07MAY2014 /9	Unknown/NA	C	6	1	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	07MAY2014 /9	Unknown/NA	C	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0022/60 /M/W2/N	Musculoskeletal and connective tissue disorders/ Myopathy/ PROXIMAL MYOPATHY	22DEC2014 /21	Unknown/NA	C	6	0	1	5	1
	Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCHOLESTEROLAEMIA	01DEC2014 /0	Unknown/NA	C	6	1	1	5	1
	Skin and subcutaneous tissue disorders/ Rash/ RASH	20DEC2014 /19	Unknown/NA	C	6	0	1	3	1
	Renal and urinary disorders/ Renal impairment/ RENAL IMPAIRMENT	01DEC2014 /0	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0022/60 /M/W2/N	Gastrointestinal disorders/ Abdominal distension/ BLOATING	26JAN2015 /56	Unknown/NA	C	6	0	1	5	1
	Investigations/ Transaminases increased/ TRANSAMINITIS	12JAN2015 /42	Unknown/NA	C	6	0	2	5	3
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	22DEC2014 /21	Unknown/NA	C	6	0	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ WORSENING PERIPHERAL OEDEMA	20DEC2014 /19	Unknown/NA	C	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0022/60 /M/W2/N	Skin and subcutaneous tissue disorders/ Palmar erythema/ PALMAR ERYTHEMA	22DEC2014 /21	Unknown/NA	C	6	0	1	3	1
257-0024/75 /M/W2/N	General disorders and administration site conditions/ Injection site rash/ SKIN RASH AT INJECTION SITE	26JAN2015 /34	Unknown/NA	C	6	0	1	2	1
	Infections and infestations/ Lower respiratory tract infection/ CHEST INFECTION	11FEB2015 /50	Unknown/NA	C	6	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ LEFT SIDE MUSCULAR SKELETAL CHEST PAIN	06FEB2015 /45	Unknown/NA	I	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0024/75 /M/W2/N	Infections and infestations/ Lower respiratory tract infection/ CHEST INFECTION	26DEC2014 /3	02JAN2015 /-52	C	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Rales/ BILATERAL BASAL CREPITATIONS	05JAN2015 /13	Unknown/NA	C	6	0	1	5	1
257-0025/69 /M/BL/Y	General disorders and administration site conditions/ Fatigue/ FATIGUE	26JAN2015 /35	Unknown/NA	C	5	0	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	22DEC2014 /0	23DEC2014 /-76	I	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0026/65 /M/MIX/N	General disorders and administration site conditions/ Oedema peripheral/ PEDAL OEDEMA	09FEB2015 /21	16FEB2015 /-42	C	1	1	1	5	1
257-0027/52 /M/A6/Y	Musculoskeletal and connective tissue disorders/ Arthralgia/ TENDER RIGHT SHOULDER	16FEB2015 /28	Unknown/NA	I	6	0	1	5	1
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to central nervous system/ FRONTAL BRAIN HAEMORRHAGIC METASTASIS	18FEB2015 /30	02MAR2015 /14	C	4	1	2	5 [PD]	5
	Musculoskeletal and connective tissue disorders/ Back pain/ LOWER BACK PAIN	16FEB2015 /28	Unknown/NA	I	5	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0005/64 /M/OTH/N	Musculoskeletal and connective tissue disorders/ Muscular weakness/ LEG WEAKNESS LOWER LIMBS	11OCT2013 /60	14OCT2013 /26	C	1	0	1	5 [PD]	1
	Investigations/ Alanine aminotransferase increased/ RAISED ALT	25SEP2013 /44	01DEC2013 /74	C	1	0	1	4	1
	Investigations/ Blood alkaline phosphatase increased/ RAISED ALKALINE PHOSPHATASE	10DEC2013 /120	Unknown/NA	C	6	0	1	5	2
	Investigations/ Blood bilirubin increased/ RAISED BILIRUBIN	16OCT2013 /65	Unknown/NA	C	6	0	2	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0005/64 /M/OTH/N	Investigations/ Blood alkaline phosphatase increased/ RAISED ALK PHOS	18SEP2013 /37	09DEC2013 /82	C	1	0	1	4	3
	Investigations/ Aspartate aminotransferase increased/ RAISED AST	18SEP2013 /37	04APR2014 /198	C	1	0	1	4	2
	Investigations/ Alanine aminotransferase increased/ RAISED ALT	18SEP2013 /37	24SEP2013 /6	C	1	0	1	4	2
	Investigations/ Blood bilirubin increased/ RAISED BILIRUBIN	18SEP2013 /37	16OCT2013 /28	C	1	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0005/64 /M/OTH/N	Investigations/ Blood alkaline phosphatase increased/ RAISED ALK PHOS	04SEP2013 /23	17SEP2013 /-1	C	1	0	1	4	2
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	11OCT2013 /60	14OCT2013 /26	C	1	0	1	5 [PD]	2
	Infections and infestations/ Biliary tract infection/ BILIARY DUCT INFECTION	25SEP2013 /44	04OCT2013 /16	C	2	1	1	4 [CD]	2
	Renal and urinary disorders/ Chromaturia/ DARK URINE	20SEP2013 /39	02OCT2013 /14	C	1	0	3 /25SEP2013 /Unknown	4 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0005/64 /M/OTH/N	Metabolism and nutrition disorders/ Decreased appetite/ REDUCED APPETITE	14AUG2013 /2	30SEP2013 /12	I	1	0	1	3	1
258-0007/74 /M/W2/N	Skin and subcutaneous tissue disorders/ Palmar erythema/ PALMAR ERYTHEMA	18OCT2013 /8	01NOV2013 /14	C	1	0	1	4	1
	Infections and infestations/ Biliary tract infection/ BILIARY INFECTION	07NOV2013 /28	13NOV2013 /26	C	1	1	1	4[Biliary Tract Inflammatio n]	3
	Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	07NOV2013 /28	13NOV2013 /26	I	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0007/74 /M/W2/N	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ PAIN - BOTTOM	20OCT2013 /10	Unknown/NA	C	6	1	1	5	1
	Infections and infestations/ Tinea pedis/ ATHLETES FOOT	12OCT2013 /2	31OCT2013 /13	C	1	1	1	5	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL CRAMPS AROUND LIVER	26OCT2013 /16	Unknown/NA	I	6	1	1	5	3
	Investigations/ Blood albumin decreased/ LOW ALBUMIN	18OCT2013 /8	Unknown/NA	C	6	0	3 /25OCT2013 /Unknown	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0007/74 /M/W2/N	Investigations/ Aspartate aminotransferase increased/ RAISED AST	18OCT2013 /8	Unknown/NA	C	6	0	3 /25OCT2013 /Unknown	3	2
	Investigations/ Blood alkaline phosphatase increased/ RAISED ALP	18OCT2013 /8	Unknown/NA	C	6	0	3 /25OCT2013 /Unknown	3	3
	Nervous system disorders/ Lethargy/ LETHARGY	12OCT2013 /2	Unknown/NA	I	6	0	1	3	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	14OCT2013 /4	15OCT2013 /-3	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0008/70 /M/W2/N	Infections and infestations/ Infection/ INFECTION OF UNKNOWN SOURCE	23NOV2013 /5	05DEC2013 /17	C	1	1	1	4 [Unknown]	3
	Psychiatric disorders/ Confusional state/ CONFUSION	23NOV2013 /5	03DEC2013 /15	I	1	0	3 /25NOV2013 /Unknown	4	2
	Nervous system disorders/ Hepatic encephalopathy/ ENCEPHALOPATHY - HEPATIC CAUSE	23NOV2013 /5	05DEC2013 /17	C	1	1	2	4 [More Likely Related To Infection Rather Than Study Drug.]	3
258-0009/64 /M/W2/N	Musculoskeletal and connective tissue disorders/ Muscle spasms/ FINGER CRAMPS	18OCT2014 /150	Unknown/NA	I	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0009/64 /M/W2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	01OCT2014 /133	Unknown/NA	I	6	0	1	4	2
	Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE CRAMPS IN LEGS	01OCT2014 /133	03OCT2014 /-26	I	1	1	1	4	2
	Metabolism and nutrition disorders/ Hypomagnesaemia/ HYPOMAGNESEMIA	22SEP2014 /124	Unknown/NA	C	6	1	1	4	1
	Nervous system disorders/ Aphasia/ DYSPHASIA	22SEP2014 /124	24SEP2014 /-35	C	1	0	3 /24SEP2014 /01OCT2014	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0009/64 /M/W2/N	Nervous system disorders/ Dysarthria/ DYSARTHRI	22SEP2014 /124	24SEP2014 /-35	C	1	0	3 /22SEP2014 /01OCT2014	4	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	21SEP2014 /123	23SEP2014 /-36	I	1	1	1	4	2
	Psychiatric disorders/ Confusional state/ CONFUSION	22SEP2014 /124	24SEP2014 /-35	C	1	1	3 /24SEP2014 /01OCT2014	4[CD]	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	06SEP2014 /108	13SEP2014 /-46	I	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0009/64 /M/W2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	22AUG2014 /93	23AUG2014 /-67	I	1	0	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	22AUG2014 /93	23AUG2014 /-67	I	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ ACHING MUSCLES	17JUL2014 /57	Unknown/NA	I	6	1	1	3	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ ACHING JOINTS	17JUL2014 /57	Unknown/NA	I	6	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0009/64 /M/W2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	06AUG2014 /77	07AUG2014 /-83	I	1	0	1	4	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ ACHING MUSCLES	04JUL2014 /44	16JUL2014 /-105	I	1	1	1	3	2
	Musculoskeletal and connective tissue disorders/ Arthralgia/ ACHING JOINTS	04JUL2014 /44	16JUL2014 /-105	I	1	1	1	3	2
	Nervous system disorders/ Dysgeusia/ ALTERED TASTE	12JUN2014 /22	Unknown/NA	I	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0009/64 /M/W2/N	Musculoskeletal and connective tissue disorders/ Myalgia/ ACHING MUSCLES	11JUN2014 /21	03JUL2014 /-118	I	1	0	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	12JUN2014 /22	25JUL2014 /-96	I	1	0	1	3	1
	Nervous system disorders/ Tremor/ TREMOR - BOTH HANDS	04JUN2014 /14	Unknown/NA	I	6	0	1	4	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ ACHING JOINTS	11JUN2014 /21	03JUL2014 /-118	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0009/64 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	03JUN2014 /13	Unknown/NA	I	6	0	1	4	1
	Nervous system disorders/ Aphasia/ DYSPHASIA	02JUN2014 /12	09JUN2014 /-142	C	1	0	3 /04JUN2014 /11JUN2014	4	1
	Psychiatric disorders/ Confusional state/ CONFUSION	02JUN2014 /12	05JUN2014 /-146	C	1	0	3 /04JUN2014 /11JUN2014	4	2
	Nervous system disorders/ Transient ischaemic attack/ TRANSIENT ISCHAEMIC ATTACK	03JUN2014 /13	25JUN2014 /-126	C	3	0	3 /04JUN2014 /11JUN2014	4 [CD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0009/64 /M/W2/N	Gastrointestinal disorders/ Ascites/ ASCITES - MILD (FROM PI'S PHYSICAL EXAM ENTRY)	30MAY2014 /9	Unknown/NA	C	6	0	1	4 [CD]	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	24MAY2014 /3	28MAY2014 /-154	I	1	0	1	3	1
	General disorders and administration site conditions/ Influenza like illness/ FLU LIKE SYMPTOMS	24MAY2014 /3	28MAY2014 /-154	C	1	1	1	2	2
258-0010/53 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	20NOV2014 /169	Unknown/NA	I	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0010/53 /M/W2/N	Infections and infestations/ Oral candidiasis/ ?ORAL THRUSH - SINGLE WHITE SPOT ON TONGUE	20NOV2014 /169	Unknown/NA	C	6	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	27NOV2014 /176	Unknown/NA	I	6	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ HAEMOPTYSIS	06DEC2014 /185	07DEC2014 /25	I	1	0	1	4	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	05NOV2014 /154	13NOV2014 /1	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0010/53 /M/W2/N	Infections and infestations/ Nasopharyngitis/ HEAD COLD SYMPTOMS	20OCT2014 /138	31OCT2014 /-12	C	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Dry skin/ DRY SKIN LEFT SHIN	01OCT2014 /119	05NOV2014 /-7	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ HAEMOPTYSIS	11OCT2014 /129	16OCT2014 /-27	I	1	0	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	25SEP2014 /113	26SEP2014 /-47	I	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0010/53 /M/W2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	02OCT2014 /120	Unknown/NA	I	6	1	1	3	1
	Musculoskeletal and connective tissue disorders/ Back pain/ LOWER BACK PAIN	15SEP2014 /103	27SEP2014 /-46	C	3	1	1	5	3
	Gastrointestinal disorders/ Nausea/ NAUSEA	27AUG2014 /84	30AUG2014 /-74	I	1	1	1	3	2
	Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN LEFT MIDDLE FINGER	14AUG2014 /71	16AUG2014 /-88	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0010/53 /M/W2/N	Infections and infestations/ Hordeolum/ STYE LOWER RIGHT EYELID	11AUG2014 /68	22AUG2014 /-82	C	1	0	1	5	1
	Gastrointestinal disorders/ Mouth ulceration/ MOUTH ULCER	24JUL2014 /50	06AUG2014 /-98	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	24JUL2014 /50	06AUG2014 /-98	I	1	1	1	5	1
	Infections and infestations/ Candida infection/ GENITAL THRUSH	24JUL2014 /50	06AUG2014 /-98	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0010/53 /M/W2/N	Infections and infestations/ Oral candidiasis/ ORAL THRUSH (CANDIDA)	24JUL2014 /50	06AUG2014 /-98	C	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN INDEX FINGER LEFT HAND	10JUL2014 /36	Unknown/NA	I	6	1	1	2	2
	Musculoskeletal and connective tissue disorders/ Arthralgia/ KNEE JOINT PAIN	05JUN2014 /1	25JUN2014 /-140	I	1	1	1	2	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	13JUN2014 /9	25JUN2014 /-140	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0010/53 /M/W2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	10JUN2014 /6	13JUN2014 /-152	I	1	0	1	3	2
258-0012/66 /F/W2/N	Gastrointestinal disorders/ Abdominal pain/ RIGHT SIDED ABDOMINAL PAIN	07NOV2014 /114	Unknown/NA	I	6	1	1	4	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	17AUG2014 /32	06SEP2014 /-33	I	1	1	1	3	2
	Nervous system disorders/ Dizziness/ DIZZINESS	17AUG2014 /32	18AUG2014 /-52	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0012/66 /F/W2/N	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ LEFT SIDED MUSCULOSKELETAL CHEST PAIN	17AUG2014 /32	18AUG2014 /-52	I	1	0	1	5	2
	Psychiatric disorders/ Confusional state/ CONFUSION	27JUL2014 /11	01AUG2014 /-69	I	1	0	3 /30JUL2014 /06AUG2014	4	1
	Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	27JUL2014 /11	01AUG2014 /-69	C	1	1	1	4[Due To Insufficient Fluid Intake During Hot Weather]	3
	Infections and infestations/ Oral candidiasis/ ORAL THRUSH	23JUL2014 /7	Unknown/NA	C	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0012/66 /F/W2/N	Nervous system disorders/ Dizziness/ DIZZINESS	21JUL2014 /5	21JUL2014 /-80	C	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ LEFT SIDED MUSCOSKELETAL CHEST PAIN	18JUL2014 /2	20JUL2014 /-81	I	1	1	1	5	2
258-0015/65 /M/W2/N	Investigations/ Ammonia increased/ INCREASED AMMONIA LEVELS	02JAN2015 /30	Unknown/NA	C	6	0	1	2	2
	Reproductive system and breast disorders/ Nipple pain/ PAINFUL LEFT NIPPLE	10DEC2014 /7	Unknown/NA	I	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0015/65 /M/W2/N	Nervous system disorders/ Hepatic encephalopathy/ ENCEPHALOPATHY - HEPATIC	05JAN2015 /33	12JAN2015 /10	C	1	0	2	3	2
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	24DEC2014 /21	03JAN2015 /1	I	1	1	1	4	1
	Infections and infestations/ Nasopharyngitis/ HEAD COLD SYMPTOMS	24DEC2014 /21	28DEC2014 /-5	I	1	1	1	4	1
	Psychiatric disorders/ Confusional state/ CONFUSION	11DEC2014 /8	15DEC2014 /-18	C	1	0	3 /17DEC2014 /02JAN2015	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0015/65 /M/W2/N	Nervous system disorders/ Amnesia/ MEMORY LOSS	06DEC2014 /3	10DEC2014 /-23	I	1	0	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	05DEC2014 /2	Unknown/NA	I	6	0	1	3	1
259-0001/68 /F/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	18JUN2014 /378	16JUL2014 /35	C	1	0	2	2	3
	General disorders and administration site conditions/ Fatigue/ FATIGUE	11JUN2014 /371	17JUN2014 /6	C	1	0	1	2	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0001/68 /F/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	04JUN2014 /364	10JUN2014 /-1	C	1	0	3 /04JUN2014 /11JUN2014	2	3
	General disorders and administration site conditions/ Fatigue/ FATIGUE	20MAY2014 /349	03JUN2014 /-8	C	1	0	1	2	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	06MAY2014 /335	19MAY2014 /-23	C	1	0	3 /07MAY2014 /21MAY2014	2	3
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	05MAY2014 /334	13MAY2014 /-29	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0001/68 /F/W2/N	Eye disorders/ Ocular hyperaemia/ EYE DISORDER - RED EYE	30APR2014 /329	01MAY2014 /-41	C	1	0	1	4	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	09APR2014 /308	05MAY2014 /-37	C	1	0	1	2	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	02APR2014 /301	09APR2014 /-63	I	1	1	1	3	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	25MAR2014 /293	08APR2014 /-64	C	1	0	3 /25MAR2014 /09APR2014	2	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0001/68 /F/W2/N	Reproductive system and breast disorders/ Vaginal haemorrhage/ VAGINAL HAEMORRHAGE	07MAR2014 /275	12MAR2014 /-91	I	1	0	1	4	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	02MAR2014 /270	02MAR2014 /-101	I	1	1	1	3	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	04MAR2014 /272	24MAR2014 /-79	C	1	0	1	2	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	23FEB2014 /263	03MAR2014 /-100	C	1	0	1	2	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0001/68 /F/W2/N	Reproductive system and breast disorders/ Vaginal haemorrhage/ VAGINAL HAEMORRHAGE	03MAR2014 /271	04MAR2014 /-99	I	1	0	1	4	1
	Nervous system disorders/ Dizziness/ DIZZINESS	03MAR2014 /271	04MAR2014 /-99	I	1	0	1	4	1
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	03MAR2014 /271	01JUL2014 /20	I	1	1	1	5	1
	Psychiatric disorders/ Anxiety/ ANXIETY	12FEB2014 /252	22AUG2014 /72	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0001/68 /F/W2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	03FEB2014 /243	22AUG2014 /72	C	1	1	1	3	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	17JAN2014 /226	02FEB2014 /-129	C	1	1	1	3	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	17JAN2014 /226	02FEB2014 /-129	C	1	1	3 /22JAN2014 /05FEB2014	3	3
	Gastrointestinal disorders/ Vomiting/ VOMITING	26DEC2013 /204	16JAN2014 /-146	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0001/68 /F/W2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	26DEC2013 /204	16JAN2014 /-146	C	1	1	1	3	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	11DEC2013 /189	24DEC2013 /-169	I	1	1	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	11DEC2013 /189	24DEC2013 /-169	I	1	1	1	3	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	01DEC2013 /179	16JUL2014 /35	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0001/68 /F/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	06JAN2014 /215	22AUG2014 /72	C	1	0	1	2	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	16DEC2013 /194	22AUG2014 /72	C	1	1	1	3	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	16DEC2013 /194	05JAN2014 /-157	C	1	0	3 /18DEC2013 /08JAN2014	2	3
	Gastrointestinal disorders/ Vomiting/ VOMITING	24DEC2013 /202	25DEC2013 /-168	C	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0001/68 /F/W2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	24DEC2013 /202	25DEC2013 /-168	I	1	1	1	3	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	11DEC2013 /189	15DEC2013 /-178	C	1	0	1	2	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	03DEC2013 /181	10DEC2013 /-183	C	1	0	3 /03DEC2013 /11DEC2013	2	3
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	23NOV2013 /171	26NOV2013 /-197	C	1	1	1	4[Caused By Disease Under Study]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0001/68 /F/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	27NOV2013 /175	03DEC2013 /-190	C	1	0	1	2	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	13NOV2013 /161	22AUG2014 /72	C	1	1	1	5[CD]	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	12NOV2013 /160	26NOV2013 /-197	C	1	0	3 /13NOV2013 /27NOV2013	2	3
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	23OCT2013 /140	24OCT2013 /-230	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0001/68 /F/W2/N	Nervous system disorders/ Lethargy/ LETHARGY	30OCT2013 /147	09JUL2014 /28	C	1	0	1	2	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	30OCT2013 /147	11NOV2013 /-212	C	1	0	1	2	2
	Nervous system disorders/ Lethargy/ LETHARGY	22OCT2013 /139	29OCT2013 /-225	C	1	0	3 /23OCT2013 /30OCT2013	2	3
	General disorders and administration site conditions/ Fatigue/ FATIGUE	22OCT2013 /139	29OCT2013 /-225	C	1	0	3 /23OCT2013 /30OCT2013	2	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0001/68 /F/W2/N	Nervous system disorders/ Lethargy/ LETHARGY	25SEP2013 /112	22OCT2013 /-232	C	1	0	1	2	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	25SEP2013 /112	22OCT2013 /-232	C	1	0	1	2	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	12SEP2013 /99	14SEP2013 /-270	C	1	0	1	3	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	10SEP2013 /97	24SEP2013 /-260	C	1	0	3 /11SEP2013 /25SEP2013	2	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0001/68 /F/W2/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	05SEP2013 /92	12SEP2013 /-272	C	1	1	1	4[Unrelated Constipation]	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	03SEP2013 /90	09SEP2013 /-275	C	1	0	1	2	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	03SEP2013 /90	24SEP2013 /-260	C	1	1	1	3	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	28AUG2013 /84	03SEP2013 /-281	C	1	0	3 /28AUG2013 /04SEP2013	2	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0001/68 /F/W2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	28AUG2013 /84	03SEP2013 /-281	C	1	1	3 /28AUG2013 /04SEP2013	3	3
	General disorders and administration site conditions/ Pain/ PAIN	16AUG2013 /72	19AUG2013 /-296	I	1	1	1	4	2
	Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	12JUL2013 /37	23JUL2013 /-323	C	1	1	3 /17JUL2013 /24JUL2013	3	3
	Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	28JUN2013 /23	09JUL2013 /-337	C	1	1	3 /03JUL2013 /10JUL2013	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0001/68 /F/W2/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSпноEA	22JUN2013 /17	Unknown/NA	I	6	0	1	3	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	16JUN2013 /11	16JUN2013 /-360	I	1	1	1	3	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	12JUN2013 /7	28AUG2013 /-287	C	1	0	1	2	2
	Skin and subcutaneous tissue disorders/ Rash/ RASH	12JUN2013 /7	10JUL2013 /-336	C	1	1	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0001/68 /F/W2/N	Gastrointestinal disorders/ Vomiting/ VOMITING	05SEP2013 /92	24SEP2013 /-260	I	1	1	1	3	2
259-0002/54 /F/W2/N	Nervous system disorders/ Neuropathy peripheral/ PERIPHERAL NEUROPATHY	30OCT2013 /49	Unknown/NA	C	6	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	18DEC2013 /98	08JAN2014 /42	I	1	0	1	5	1
	Infections and infestations/ Urinary tract infection/ URINE INFECTION	15NOV2013 /65	18NOV2013 /-9	C	1	1	1	2	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0002/54 /F/W2/N	Infections and infestations/ Vaginal infection/ VAGINAL INFECTION	12NOV2013 /62	17NOV2013 /-10	C	1	1	1	5	2
	Infections and infestations/ Cystitis/ CYSTITIS	06NOV2013 /56	17NOV2013 /-10	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	13OCT2013 /32	23OCT2013 /-35	C	1	1	1	4[CD]	1
	Infections and infestations/ Nasopharyngitis/ COMMON COLD	13OCT2013 /32	23OCT2013 /-35	C	1	1	1	4[CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0002/54 /F/W2/N	Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES - MYALGIA	09OCT2013 /28	Unknown/NA	C	6	0	1	2	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE ACHES - MYALGIA	25SEP2013 /14	09OCT2013 /-49	C	1	0	1	2	2
	Skin and subcutaneous tissue disorders/ Erythema multiforme/ ERYTHEMA MULTIFORME - LEFT BUTTOCK	25SEP2013 /14	09OCT2013 /-49	C	1	0	1	1	1
	Skin and subcutaneous tissue disorders/ Erythema multiforme/ ERYTHEMA MULTIFORME - RIGHT BUTTOCK	18SEP2013 /7	09OCT2013 /-49	C	1	0	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
260-0003/81 /M/A7/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	01APR2015 /147	04APR2015 /-95	C	1	3	1	5	3
	Musculoskeletal and connective tissue disorders/ Flank pain/ RIGHT SIDED FLANK (UPPER QUADRANT) PAIN	04MAR2015 /119	Unknown/NA	C	6	1	1	4	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	10JAN2015 /66	Unknown/NA	I	6	1	1	4	1
	General disorders and administration site conditions/ Injection site pain/ PAIN IN RIGHT THIGH AT INJECTION SITE	07JAN2015 /63	13JAN2015 /-176	C	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
260-0003/81 /M/A7/N	Skin and subcutaneous tissue disorders/ Rash/ RASH BEHIND KNEE	10DEC2014 /35	17DEC2014 /-203	C	1	1	1	3	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	07DEC2014 /32	17DEC2014 /-203	I	2	1	1	4	1
	Vascular disorders/ Hypotension/ HYPOTENSION	19NOV2014 /14	Unknown/NA	I	6	0	1	4	1
301-0005/61 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Wheezing/ WHEEZING	11SEP2012 /110	24NOV2012 /107	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
301-0005/61 /M/A2/Y	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	14JUN2012 /21	24NOV2012 /107	I	1	0	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ WORSENING LOWER LEG EDEMA	14JUN2012 /21	24NOV2012 /107	C	1	1	1	5	2
	Injury, poisoning and procedural complications/ Joint injury/ LEFT WRIST FALLING INJURY	02AUG2012 /70	09AUG2012 /0	I	1	2	1	5	2
	Gastrointestinal disorders/ Gastrointestinal haemorrhage/ GATROINTESTINAL BLEEDING	05JUL2012 /42	19JUL2012 /-21	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
301-0005/61 /M/A2/Y	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRALGIA	07JUN2012 /14	Unknown/NA	C	6	1	1	5	1
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	07JUN2012 /14	09AUG2012 /0	I	1	0	1	3	1
301-0007/55 /F/A2/Y	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	08FEB2013 /35	26MAR2013 /11	C	1	0	1	5	2
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	22FEB2013 /49	26MAR2013 /11	C	1	1	1	3	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
301-0007/55 /F/A2/Y	Investigations/ Electrocardiogram QT prolonged/ PROLONGED QT	25JAN2013 /21	07MAR2013 /-8	C	1	0	1	3	2
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	06MAR2013 /61	26MAR2013 /11	I	1	1	1	5	3
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	21JAN2013 /17	05MAR2013 /-10	I	1	1	1	5	2
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	01FEB2013 /28	26MAR2013 /11	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
301-0007/55 /F/A2/Y	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	18JAN2013 /14	26MAR2013 /11	I	1	0	1	5	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	25JAN2013 /21	26MAR2013 /11	C	1	1	1	5	2
	Skin and subcutaneous tissue disorders/ Pruritus generalised/ GENERAL PRURITUS	10JAN2013 /6	26MAR2013 /11	I	1	1	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	10JAN2013 /6	26MAR2013 /11	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
301-0007/55 /F/A2/Y	General disorders and administration site conditions/ Pain/ GENERAL SORENESS	10JAN2013 /6	26MAR2013 /11	I	1	1	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS (LEGS)	25JAN2013 /21	08FEB2013 /-35	C	1	0	1	5	1
	Gastrointestinal disorders/ Oesophageal varices haemorrhage/ ESOPHAGEAL VARICES BLEEDING	16MAR2013 /71	26MAR2013 /11	C	4	3	2	5 [PD]	4
301-0009/55 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	26MAR2013 /74	01MAY2013 /43	C	1	2	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
301-0009/55 /M/A2/N	Blood and lymphatic system disorders/ Leukocytosis/ LEUKOCYTOSIS	28MAR2013 /76	05APR2013 /17	C	1	0	1	5	1
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	28MAR2013 /76	01MAY2013 /43	C	1	0	1	5	2
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	28MAR2013 /76	01MAY2013 /43	C	1	0	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ LOWER LEG EDEMA	19MAR2013 /67	01MAY2013 /43	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
301-0009/55 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	14MAR2013 /62	01MAY2013 /43	C	1	2	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	14MAR2013 /62	01MAY2013 /43	C	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	07MAR2013 /55	01MAY2013 /43	C	1	1	1	5	3
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	01MAR2013 /49	01MAY2013 /43	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
301-0009/55 /M/A2/N	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	01MAR2013 /49	01MAR2013 /-18	C	1	1	1	5	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	17JAN2013 /6	07MAR2013 /-12	C	1	1	1	5	2
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASHES	20JAN2013 /9	07MAR2013 /-12	C	1	1	3 /24JAN2013 /07FEB2013	3	2
302-0002/32 /F/A2/Y	Metabolism and nutrition disorders/ Hypoglycaemia/ HYPOGLYCEMIA	13DEC2011 /35	15DEC2011 /16	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0002/32 /F/A2/Y	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	13DEC2011 /35	15DEC2011 /16	C	1	0	1	5	1
	Blood and lymphatic system disorders/ Leukocytosis/ LEUKOCYTOSIS	29NOV2011 /21	15DEC2011 /16	C	1	0	1	5	3
	Eye disorders/ Eye disorder/ EYE DISORDERS - OTHER, SPECIFY	19NOV2011 /11	01DEC2011 /2	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	13DEC2011 /35	15DEC2011 /16	C	1	0	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0002/32 /F/A2/Y	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	29NOV2011 /21	15DEC2011 /16	C	1	0	1	5	2
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH	01DEC2011 /23	02DEC2011 /3	C	1	1	1	3	2
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	13DEC2011 /35	15DEC2011 /16	C	1	1	1	4	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	07DEC2011 /29	15DEC2011 /16	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0002/32 /F/A2/Y	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	13DEC2011 /35	15DEC2011 /16	C	1	1	1	4	3
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	25NOV2011 /17	13DEC2011 /14	C	1	1	1	4	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	13DEC2011 /35	15DEC2011 /16	I	1	0	1	4	2
	General disorders and administration site conditions/ Injection site reaction/ INJECTION SITE REACTION	25NOV2011 /17	28NOV2011 /-1	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0002/32 /F/A2/Y	Investigations/ Aspartate aminotransferase increased/ ASPARATE AMINOTRANSFERASE INCREASED	29NOV2011 /21	15DEC2011 /16	C	1	0	3 /06DEC2011 /Unknown	5 [PD]	3
	Skin and subcutaneous tissue disorders/ Rash maculo-papular/ RASH MACULO-PAPULAR	24NOV2011 /16	28NOV2011 /-1	I	1	1	1	3	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	24NOV2011 /16	13DEC2011 /14	I	1	0	1	4	1
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	13DEC2011 /35	15DEC2011 /16	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0002/32 /F/A2/Y	Hepatobiliary disorders/ Hepatic failure/ HEPATIC FAILURE	13DEC2011 /35	15DEC2011 /16	C	1	0	1	4	3
	General disorders and administration site conditions/ Injection site reaction/ INJECTION SITE REACTION (RIGHT ARM)	17NOV2011 /9	24NOV2011 /-5	C	1	1	3 /22NOV2011 /29NOV2011	3	2
	Gastrointestinal disorders/ Upper gastrointestinal haemorrhage/ UPPER GASTRONITESTINAL HEMORRHAGE	13DEC2011 /35	15DEC2011 /16	C	1	3	1	4	3
	Gastrointestinal disorders/ Nausea/ NAUSEA	06DEC2011 /28	15DEC2011 /16	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0002/32 /F/A2/Y	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	05DEC2011 /27	13DEC2011 /14	C	1	1	1	4	3
	Musculoskeletal and connective tissue disorders/ Myositis/ MYOSITIS	17NOV2011 /9	22NOV2011 /-7	C	1	0	1	3	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	06DEC2011 /28	15DEC2011 /16	C	1	1	1	4	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	13DEC2011 /35	15DEC2011 /16	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0002/32 /F/A2/Y	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	13DEC2011 /35	15DEC2011 /16	C	1	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Muscular weakness/ GENERALIZED MUSCLE WEAKNESS	08DEC2011 /30	15DEC2011 /16	C	1	1	1	5	2
	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	29NOV2011 /21	13DEC2011 /14	C	1	0	1	5	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	13DEC2011 /35	15DEC2011 /16	C	1	2	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0002/32 /F/A2/Y	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	13DEC2011 /35	15DEC2011 /16	C	1	0	1	5	1
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT NEOPLASM PROGRESSION	13DEC2011 /35	15DEC2011 /16	C	4	0	2	5 [PD]	4
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	29NOV2011 /21	15DEC2011 /16	C	1	0	1	5 [PD]	2
	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	13DEC2011 /35	15DEC2011 /16	C	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0002/32 /F/A2/Y	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	13DEC2011 /35	15DEC2011 /16	C	1	1	1	4	2
	Skin and subcutaneous tissue disorders/ Rash maculo-papular/ RASH MACULO-PAPULAR	12DEC2011 /34	15DEC2011 /16	C	1	1	1	4	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	13DEC2011 /35	15DEC2011 /16	C	1	1	1	4	2
	Investigations/ International normalised ratio increased/ INR INCREASED	13DEC2011 /35	15DEC2011 /16	C	1	2	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0002/32 /F/A2/Y	Musculoskeletal and connective tissue disorders/ Arthralgia/ BOTH KNEES PAIN	22NOV2011 /14	25NOV2011 /-4	C	1	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ BOTH KNEES PAIN	19NOV2011 /11	22NOV2011 /-7	C	1	1	1	4	2
302-0004/57 /M/A2/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT NEOPLASM PROGRESSION	20MAR2012 /70	21MAR2012 /22	C	4	0	2	5 [PD]	4
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to lung/ LUNG METASTASIS	16MAR2012 /66	21MAR2012 /22	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0004/57 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	29FEB2012 /50	21MAR2012 /22	C	1	0	1	5	1
	Renal and urinary disorders/ Dysuria/ DIFFICULTY IN VOIDING	15MAR2012 /65	21MAR2012 /22	C	1	3	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Sputum increased/ MUCH SPUTUM	08MAR2012 /58	21MAR2012 /22	C	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ HEMOPTYSIS	03MAR2012 /53	21MAR2012 /22	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0004/57 /M/A2/Y	Infections and infestations/ Cellulitis/ RIGHT LOWER LEG CELLULITIS (SKIN INFECTION)	28FEB2012 /49	21MAR2012 /22	C	1	1	1	5	3
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENTION	14FEB2012 /35	21MAR2012 /22	C	1	3	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ LEG EDEMA	01FEB2012 /22	28FEB2012 /0	C	1	1	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	17JAN2012 /7	24JAN2012 /-35	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0004/57 /M/A2/Y	Psychiatric disorders/ Insomnia/ INSOMNIA	17JAN2012 /7	10FEB2012 /-18	C	1	1	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	28FEB2012 /49	21MAR2012 /22	C	1	3	3 /06MAR2012 /Unknown	5[CD]	3
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	28FEB2012 /49	21MAR2012 /22	I	1	1	1	5[PD]	3
	Gastrointestinal disorders/ Ascites/ ASCITES	28FEB2012 /49	21MAR2012 /22	C	1	3	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0004/57 /M/A2/Y	Metabolism and nutrition disorders/ Hypophagia/ POOR FOOD INTAKE	16MAR2012 /66	21MAR2012 /22	C	1	1	1	5	1
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	13MAR2012 /63	21MAR2012 /22	C	1	1	1	5	4
302-0007/76 /M/A2/Y	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	01MAY2012 /77	23MAR2013 /326	C	1	0	1	5	2
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	12JUN2012 /119	23MAR2013 /326	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0007/76 /M/A2/Y	Nervous system disorders/ Spinal cord compression/ SPINAL CORD COMPRESSION	08MAY2012 /84	23MAR2013 /326	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	14MAY2012 /90	21MAY2012 /20	C	1	1	1	5	2
	Gastrointestinal disorders/ Stomatitis/ MUCOSITIS ORAL	07MAY2012 /83	07MAY2012 /6	C	1	1	1	5	2
	Gastrointestinal disorders/ Gastrointestinal motility disorder/ DIFFICULT TO DEFECATE	17APR2012 /63	23MAR2013 /326	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0007/76 /M/A2/Y	Gastrointestinal disorders/ Duodenal ulcer/ DUODENAL ULCER	03APR2012 /49	23MAR2013 /326	C	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Bone pain/ BONE PAIN,RIGHT KNEE	13MAR2012 /28	23MAR2013 /326	I	1	1	1	5	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	20MAR2012 /35	27MAR2012 /-35	I	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Back pain/ LOW BACK PAIN	28FEB2012 /14	23MAR2013 /326	I	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0007/76 /M/A2/Y	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	20MAR2012 /35	03APR2012 /-28	C	1	0	1	5	1
	Investigations/ Blood lactate dehydrogenase increased/ LACTIC DEHYDROGENASE INCREASED	01MAY2012 /77	23MAR2013 /326	C	1	0	1	5	1
302-0008/37 /M/A2/Y	General disorders and administration site conditions/ Oedema/ PITTING EDEMA	14MAY2012 /76	07SEP2012 /122	C	1	1	1	5	2
	General disorders and administration site conditions/ Oedema/ PITTING EDEMA	14MAR2012 /15	03APR2012 /-35	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0008/37 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Wheezing/ WHEEZING	29MAY2012 /91	07SEP2012 /122	I	1	1	1	5	3
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	29MAY2012 /91	07SEP2012 /122	C	1	1	1	5	2
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH	26MAY2012 /88	01JUN2012 /24	C	1	1	1	5	1
	General disorders and administration site conditions/ Puncture site haemorrhage/ BLOODY SAMPLING SITE	19MAY2012 /81	27MAY2012 /19	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0008/37 /M/A2/Y	Musculoskeletal and connective tissue disorders/ Back pain/ LOW BACK PAIN	17MAY2012 /79	07SEP2012 /122	I	1	1	1	5	1
	Gastrointestinal disorders/ Haemorrhagic ascites/ BLOODY ASCITES	13MAR2012 /14	10JUN2012 /33	C	1	1	1	5	2
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Tumour haemorrhage/ HEPATOMA BLEEDING	14MAY2012 /76	10JUN2012 /33	C	1	3	1	5	3
	Infections and infestations/ Gastroenteritis/ ACUTE GASTROENTERITIS	24APR2012 /56	27APR2012 /-11	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0008/37 /M/A2/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	01MAY2012 /63	02MAY2012 /-6	I	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	14MAY2012 /76	07SEP2012 /122	C	1	0	1	5	3
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	14MAY2012 /76	13JUN2012 /36	C	1	1	1	5 [PD]	3
	Musculoskeletal and connective tissue disorders/ Groin pain/ INGUINAL PAIN	18APR2012 /50	24APR2012 /-14	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0008/37 /M/A2/Y	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	21MAR2012 /22	06APR2012 /-32	I	1	1	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	01MAY2012 /63	02MAY2012 /-6	I	1	1	1	5	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	08MAY2012 /70	07SEP2012 /122	I	1	0	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	27MAR2012 /28	17APR2012 /-21	C	1	0	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0008/37 /M/A2/Y	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	08MAY2012 /70	14MAY2012 /6	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	01MAY2012 /63	10MAY2012 /2	C	1	0	1	5	1
	Nervous system disorders/ Dizziness/ DIAZZINESS	24APR2012 /56	24APR2012 /-14	C	1	0	1	1	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	24APR2012 /56	24APR2012 /-14	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0008/37 /M/A2/Y	Skin and subcutaneous tissue disorders/ Cold sweat/ COOL SWEATING	24APR2012 /56	24APR2012 /-14	C	1	0	1	1	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	27MAR2012 /28	01APR2012 /-37	C	1	0	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	27MAR2012 /28	03APR2012 /-35	I	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	14MAR2012 /15	03APR2012 /-35	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0008/37 /M/A2/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	13MAR2012 /14	23MAR2012 /-46	I	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	28FEB2012 /0	04MAR2012 /-65	I	1	0	1	5	1
	Hepatobiliary disorders/ Hepatic haemorrhage/ HEPATIC HEMORRHAGE	13MAR2012 /14	23MAR2012 /-46	C	1	3	3 /13MAR2012 /27MAR2012	5 [PD]	3
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	17MAR2012 /18	27MAR2012 /-42	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0008/37 /M/A2/Y	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	13MAR2012 /14	21MAR2012 /-48	C	1	1	1	5	2
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	18MAR2012 /19	23MAR2012 /-46	I	1	1	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	27MAR2012 /28	30MAR2012 /-39	I	1	0	1	5	1
	General disorders and administration site conditions/ Hernia/ HERNIA	18APR2012 /50	21APR2012 /-17	C	1	1	1	5[Not Related Hcc]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0008/37 /M/A2/Y	Immune system disorders/ Anaphylactic shock/ ANAPHYLACTIC SHOCK	01MAY2012 /63	02MAY2012 /-6	C	1	1	1	1	3
302-0010/45 /M/A2/Y	Psychiatric disorders/ Insomnia/ INSOMNIA	31JUL2012 /105	08DEC2012 /158	C	1	1	1	5	1
	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	03JUL2012 /77	08DEC2012 /158	C	1	0	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	03JUL2012 /77	08DEC2012 /158	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0010/45 /M/A2/Y	Musculoskeletal and connective tissue disorders/ Back pain/ LOW BACK PAIN	25JUN2012 /69	08DEC2012 /158	I	1	0	1	5	1
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	19JUN2012 /63	08DEC2012 /158	C	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ BOTH SHOULDER PAIN	19JUN2012 /63	26JUN2012 /-7	C	1	1	1	5	1
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	05JUN2012 /49	03JUL2012 /0	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0010/45 /M/A2/Y	Investigations/ Neutrophil count decreased/ NEUTROPHIL COUNT DECREASED	08MAY2012 /21	22MAY2012 /-42	C	1	0	3 /08MAY2012 /15MAY2012	5	3
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ SHOULDER PAIN	26JUN2012 /70	03JUL2012 /0	C	1	1	1	4 [PD]	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	19JUN2012 /63	08DEC2012 /158	I	1	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIGHT SHOULDER PAIN	05JUN2012 /49	19JUN2012 /-14	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0010/45 /M/A2/Y	General disorders and administration site conditions/ Fatigue/ FATIGUE	22MAY2012 /35	08DEC2012 /158	I	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT DISCOMFORT	22MAY2012 /35	12JUN2012 /-21	I	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	01MAY2012 /14	12JUN2012 /-21	I	1	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ SHOULDER PAIN	03JUL2012 /77	08DEC2012 /158	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0010/45 /M/A2/Y	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	19JUN2012 /63	08DEC2012 /158	C	1	0	1	5	1
302-0011/52 /M/A2/Y	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	05JUN2012 /42	06JUN2012 /22	C	1	0	1	5	3
	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	22MAY2012 /28	06JUN2012 /22	C	1	0	1	5	2
	Gastrointestinal disorders/ Abdominal pain upper/ LEFT UPPER QUADRANT PAIN	20MAY2012 /26	06JUN2012 /22	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0011/52 /M/A2/Y	Psychiatric disorders/ Insomnia/ INSOMNIA	20MAY2012 /26	06JUN2012 /22	C	1	1	1	5	1
	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	01MAY2012 /7	21MAY2012 /6	C	1	0	1	5	1
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	05JUN2012 /42	06JUN2012 /22	C	4	0	1	5 [PD]	4
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	15MAY2012 /21	04JUN2012 /20	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0011/52 /M/A2/Y	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	22MAY2012 /28	06JUN2012 /22	C	1	1	3 /22MAY2012 /Unknown	5	3
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	01MAY2012 /7	21MAY2012 /6	C	1	1	1	5	2
	General disorders and administration site conditions/ Oedema/ BOTH LEG PITTING EDEMA	29MAY2012 /35	06JUN2012 /22	C	1	1	1	4	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	29MAY2012 /35	06JUN2012 /22	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0011/52 /M/A2/Y	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	15MAY2012 /21	28MAY2012 /13	C	1	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Hiccups/ HICCUP	08MAY2012 /14	20MAY2012 /5	I	1	0	1	5	1
302-0015/60 /M/A2/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	12JUL2013 /87	15JUL2013 /13	C	1	1	1	5	1
	Investigations/ Weight decreased/ WEIGHT LOSS	14MAY2013 /28	10MAR2014 /251	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0015/60 /M/A2/Y	Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE SORENESS (BACK AND FLANK)	02JUL2013 /77	09JUL2013 /7	C	1	0	1	4	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	25JUN2013 /70	02JUL2013 /0	C	1	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH (SCANTY SPUTUM)	09JUN2013 /54	23JUN2013 /-9	C	1	0	1	5	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	01AUG2013 /107	02AUG2013 /31	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0015/60 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH (BLOODY SPUTUM)	23JUN2013 /68	29JUL2013 /27	I	1	1	1	5	1
302-0016/60 /M/A2/N	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH	06AUG2013 /112	15OCT2013 /105	C	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Bronchitis chronic/ CHRONIC BRONCHITIS	09JUL2013 /84	03SEP2013 /63	C	1	1	1	5	1
	Skin and subcutaneous tissue disorders/ Erythema/ ERYTHEMA	30APR2013 /14	07MAY2013 /-56	C	1	1	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0016/60 /M/A2/N	Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEG SORENESS	14MAY2013 /28	28JAN2014 /210	C	1	1	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	07MAY2013 /21	21MAY2013 /-42	C	1	1	1	4	2
	Psychiatric disorders/ Insomnia/ INSOMNIA	30APR2013 /14	07SEP2013 /67	C	1	1	1	4	1
302-0019/52 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH (BLOODY SPUTUM)	04JUN2013 /21	Unknown/NA	I	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0022/65 /M/A2/Y	Musculoskeletal and connective tissue disorders/ Back pain/ LOW BACK PAIN	13AUG2013 /35	05OCT2013 /18	C	1	0	1	4	1
	Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	03OCT2013 /86	05OCT2013 /18	C	1	1	1	5	3
	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH (BLOODY SPUTUM)	03OCT2013 /86	05OCT2013 /18	I	1	1	1	5	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	27SEP2013 /80	05OCT2013 /18	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0022/65 /M/A2/Y	Psychiatric disorders/ Insomnia/ INSOMNIA	27SEP2013 /80	04OCT2013 /17	C	1	1	1	5	1
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH(INGUINAL)	26SEP2013 /79	05OCT2013 /18	C	1	1	1	5	1
	Psychiatric disorders/ Anxiety/ ANXIETY	22SEP2013 /75	05OCT2013 /18	C	1	1	1	4	1
	Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIA	22SEP2013 /75	02OCT2013 /15	I	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0022/65 /M/A2/Y	Vascular disorders/ Hypertension/ HYPERTENSION	22SEP2013 /75	05OCT2013 /18	I	1	1	1	4	3
	General disorders and administration site conditions/ Gait disturbance/ GAIT DISTURBANCE	10SEP2013 /63	05OCT2013 /18	C	1	0	1	4	1
	Nervous system disorders/ Haemorrhage intracranial/ INTRACRANIAL HEMORRHAGE	22SEP2013 /75	05OCT2013 /18	C	4	1	2	5 [PD]	4
	Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA (BOTH LOWER EXTREMITIES)	13AUG2013 /35	22SEP2013 /5	C	1	1	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0022/65 /M/A2/Y	Skin and subcutaneous tissue disorders/ Palmar-plantar erythrodysaesthesia syndrome/ PALMAR-PLANTAR ERYTHRODYSESTHESIA SYNDROME	17JUL2013 /8	22SEP2013 /5	C	1	0	1	2	1
302-0023/68 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Hiccups/ HICCUP	15OCT2013 /35	19NOV2013 /35	I	1	1	1	4	1
	Injury, poisoning and procedural complications/ Procedural pain/ PTCD INSERTION SITE PAIN	25OCT2013 /45	28OCT2013 /13	C	1	1	1	5	1
	General disorders and administration site conditions/ Puncture site reaction/ LOCAL ERYTHEMATOUS IN PTCD PUNCTURE SITE	14NOV2013 /65	19NOV2013 /35	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0023/68 /M/A2/N	Skin and subcutaneous tissue disorders/ Eczema asteatotic/ ASTEATOTIC ECZEMA ON THE LOWER LIMBS	14NOV2013 /65	19NOV2013 /35	C	1	0	1	4	1
	Skin and subcutaneous tissue disorders/ Lichenification/ DIFFUSE LICHENIFIED PLAQUES	14NOV2013 /65	19NOV2013 /35	C	1	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT ARM PAUNFUL	01OCT2013 /21	22OCT2013 /7	C	1	0	1	4	1
	Injury, poisoning and procedural complications/ Procedural haemorrhage/ PTCD TUBE INSERTION SITE MILD BLEEDING	20OCT2013 /40	28OCT2013 /13	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0023/68 /M/A2/N	Injury, poisoning and procedural complications/ Procedural complication/ PTCD TUBE DISLOCATION	20OCT2013 /40	25OCT2013 /10	I	1	3	1	5	1
	Immune system disorders/ Hypersensitivity/ ALLERGIC REACTION	08OCT2013 /28	15OCT2013 /0	I	1	1	1	1	2
	Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE SORENESS	17SEP2013 /7	22OCT2013 /7	C	1	1	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	17SEP2013 /7	24SEP2013 /-21	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0023/68 /M/A2/N	Immune system disorders/ Hypersensitivity/ ALLERGIC REACTION	10SEP2013 /0	11SEP2013 /-34	C	1	1	1	1	2
302-0024/66 /F/A2/N	Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING LOW BACK PAIN	08OCT2013 /14	23NOV2013 /-17	C	1	1	1	5	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	07JAN2014 /105	09APR2015 /485	C	1	0	1	5	1
	Psychiatric disorders/ Anxiety/ ANXIETY	07JAN2014 /105	09APR2015 /485	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0024/66 /F/A2/N	General disorders and administration site conditions/ Catheter site haemorrhage/ PORT-A WOUND ECCHYMOSIS	30DEC2013 /97	02JAN2014 /23	C	1	1	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	13DEC2013 /80	17DEC2013 /7	C	1	1	1	4	1
	Infections and infestations/ Conjunctivitis/ CONJUNCTIVITIS INFECTIVE	06DEC2013 /73	03JAN2014 /24	C	1	1	1	5	2
	Eye disorders/ Dry eye/ DRY EYE	06DEC2013 /73	03JAN2014 /24	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0025/40 /M/A2/Y	Nervous system disorders/ Haemorrhage intracranial/ INTRACRANIAL HEMORRHAGE	08NOV2013 /17	06JUL2014 /243	C	1	1	2	3	3
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	22OCT2013 /0	29OCT2013 /-7	C	1	0	1	5	1
302-0026/49 /M/A2/Y	Infections and infestations/ Infection/ INFECTIO	12JAN2014 /61	13JAN2014 /-183	C	1	1	1	5	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	29JUL2014 /259	22SEP2014 /69	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0026/49 /M/A2/Y	Psychiatric disorders/ Insomnia/ INSOMNIA	24JUN2014 /224	Unknown/NA	C	6	1	1	4	1
	Gastrointestinal disorders/ Faeces discoloured/ DARK STOOL	08JUL2014 /238	22JUL2014 /7	C	1	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE SORENESS (BACK AND ABDOMEN)	17JUN2014 /217	24JUN2014 /-21	C	1	1	1	4	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	29APR2014 /168	08MAY2014 /-68	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0026/49 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORETHROAT	08APR2014 /147	15APR2014 /-91	C	1	1	1	4	2
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	10APR2014 /149	15APR2014 /-91	C	1	1	1	4	2
	Musculoskeletal and connective tissue disorders/ Myofascial pain syndrome/ MYOFASCIAL PAIN	09JAN2014 /58	10JAN2014 /-186	C	1	0	1	4	1
	General disorders and administration site conditions/ Malaise/ MALAISE	08JAN2014 /57	10JAN2014 /-186	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0026/49 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	17DEC2013 /35	04MAR2014 /-133	C	1	1	1	4	2
	Psychiatric disorders/ Insomnia/ INSOMNIA	18FEB2014 /98	04MAR2014 /-133	C	1	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	10JAN2014 /59	10JAN2014 /-186	C	1	1	1	4	1
	Skin and subcutaneous tissue disorders/ Palmar-plantar erythrodysaesthesia syndrome/ PALMAR-PLANTAR ERYTHRODYSESTHESIA SYNDROME	17DEC2013 /35	22MAY2014 /-54	I	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0026/49 /M/A2/Y	Infections and infestations/ Infection/ INFECTION	08JAN2014 /57	11JAN2014 /-185	C	1	1	1	5[Infection ]	3
	Skin and subcutaneous tissue disorders/ Rash maculo-papular/ RASH MACULO-PAPULAR	19NOV2013 /7	26NOV2013 /-231	C	1	0	1	4	1
303-0001/50 /M/A2/N	Gastrointestinal disorders/ Ascites/ ASCITES	18APR2012 /75	08AUG2012 /112	C	1	1	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ ANKLE EDEMA	22FEB2012 /19	29FEB2012 /-49	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
303-0001/50 /M/A2/N	Gastrointestinal disorders/ Ascites/ WORSENING OF ASCITES	22FEB2012 /19	06MAR2012 /-43	C	1	1	1	4	2
	Gastrointestinal disorders/ Abdominal distension/ WORSENING OF ABDOMEN DISTENSION	22FEB2012 /19	06MAR2012 /-43	C	2	0	1	4	2
	Gastrointestinal disorders/ Abdominal pain upper/ UPPER ABDOMEN PAIN	15FEB2012 /12	28FEB2012 /-50	I	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMEN DISTENSION	18MAY2012 /105	21NOV2012 /217	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
303-0003/47 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ COUGH WITH HEMOPTYSIS	19DEC2012 /21	23JAN2013 /-23	I	1	1	1	5	2
	Infections and infestations/ Biliary tract infection/ CATHETER-RELATED BILIARY TRACT INFECTION	24JAN2013 /57	08FEB2013 /-7	C	1	3	3 /30JAN2013 /15FEB2013	5[Catheter- Related Biliay Tract Infection]	3
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	30JAN2013 /63	20APR2013 /64	I	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ BILATERAL CHEST WALL PAIN	29JAN2013 /62	30JAN2013 /-16	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
303-0003/47 /M/A2/Y	Infections and infestations/ Biliary tract infection/ CATHETER-RELATED BILIARY TRACT INFECTION	06MAR2013 /98	12MAR2013 /25	C	1	3	1	5[Unknow]	3
	General disorders and administration site conditions/ Chest discomfort/ PRECORDIAL CHEST TIGHTNESS	12DEC2012 /14	02JAN2013 /-44	I	1	0	1	4	1
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH (BOTH LEGS AND TRUNK)	09DEC2012 /11	09JAN2013 /-37	I	1	1	1	3	2
	General disorders and administration site conditions/ Malaise/ MALAISE	28NOV2012 /0	20APR2013 /64	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
303-0003/47 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	28NOV2012* /0	05DEC2012 /-72	I	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	26JAN2013 /59	15FEB2013 /0	I	1	1	1	5	2
303-0004/18 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Cough/ WORSENING OF COUGH	30JAN2013 /51	10MAY2013 /79	I	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	13MAR2013 /93	10MAY2013 /79	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
303-0004/18 /M/A2/N	Investigations/ Weight decreased/ WEIGHT LOSS	27FEB2013 /79	10MAY2013 /79	C	1	1	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	01JAN2013* /22	16JAN2013 /-35	I	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	23JAN2013 /44	06FEB2013 /-14	I	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ ARM PAIN	19DEC2012 /9	02JAN2013 /-49	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
303-0006/64 /M/A2/N	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	18JUN2013 /69	25JUL2013 /66	I	1	1	1	5	2
	General disorders and administration site conditions/ Oedema/ EXTREME PITTING EDEMA	18JUN2013 /69	25JUL2013 /66	I	1	1	1	5	3
	Gastrointestinal disorders/ Ascites/ ASCITES	22MAY2013 /42	11JUL2013 /52	C	1	1	1	5	2
	Cardiac disorders/ Palpitations/ PALPITATION	20MAY2013 /40	18JUN2013 /29	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
303-0006/64 /M/A2/N	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Tumour pain/ PAIN DUE TO LUNG METASTASIS	10JUN2013 /61	25JUL2013 /66	I	1	1	1	5	3
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT NEOPLASM PROGRESSION	18JUN2013 /69	25JUL2013 /66	C	4	3	1	5 [PD]	3
	General disorders and administration site conditions/ Fatigue/ FATIGUE	20MAY2013 /40	25JUL2013 /66	C	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	20MAY2013 /40	25JUL2013 /66	I	1	3	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
303-0006/64 /M/A2/N	Gastrointestinal disorders/ Abdominal distension/ WORSENING OF ABDOMINAL DISTENSION	29MAY2013 /49	25JUL2013 /66	I	1	1	1	5	3
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	17APR2013 /7	29MAY2013 /9	I	1	1	1	5	2
303-0007/50 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	01OCT2013 /69	05OCT2013 /10	I	1	1	1	5	2
	Nervous system disorders/ Encephalopathy/ ENCEPHALOPATHY	27SEP2013 /65	25OCT2013 /30	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
303-0007/50 /M/A2/Y	Gastrointestinal disorders/ Gastric varices/ GASTRIC VARICES	28SEP2013 /66	25OCT2013 /30	C	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	11SEP2013 /49	25SEP2013 /0	I	1	0	1	5	1
	Gastrointestinal disorders/ Ascites/ WORSENING OF ASCITES	18OCT2013 /86	25OCT2013 /30	C	1	3	1	5	3
	Infections and infestations/ Body tinea/ TINEA COPORIS	21OCT2013 /89	25OCT2013 /30	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
303-0007/50 /M/A2/Y	General disorders and administration site conditions/ Oedema/ PITTING EDEMA	02OCT2013 /70	25OCT2013 /30	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	27SEP2013 /65	25OCT2013 /30	C	1	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	27SEP2013 /65	15OCT2013 /20	I	1	1	1	5	2
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT NEOPLASM PROGRESSION	02OCT2013 /70	25OCT2013 /30	C	4	1	1	5 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
303-0007/50 /M/A2/Y	Hepatobiliary disorders/ Liver disorder/ LIVER DECOMPENSATION	18SEP2013 /56	25OCT2013 /30	C	1	1	1	5	3
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREIXA	18SEP2013 /56	25OCT2013 /30	I	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	11SEP2013 /49	25OCT2013 /30	I	1	1	1	5	2
	Gastrointestinal disorders/ Gastrointestinal haemorrhage/ HEMORRHAGE OF GASTROINTESTINAL TRACT	27SEP2013 /65	03OCT2013 /8	C	1	3	1	5 [CD]	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
303-0007/50 /M/A2/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Tumour pain/ TUMOR PAIN	26SEP2013 /64	25OCT2013 /30	I	1	1	1	5	3
	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ LEFT CHEST WITH TENDER	28AUG2013 /35	04SEP2013 /-21	I	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING OF RIGHT KNEE PAIN	28AUG2013 /35	25OCT2013 /30	I	1	1	1	5	3
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT LEG PAIN	14AUG2013 /21	04SEP2013 /-21	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
303-0007/50 /M/A2/Y	Musculoskeletal and connective tissue disorders/ Back pain/ BACKACHE	07AUG2013 /14	28AUG2013 /-28	I	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT ELBOW PAIN	24JUL2013 /0	02AUG2013 /-54	I	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Arthralgia/ KNEE JOINT PAIN	24JUL2013 /0	28AUG2013 /-28	I	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Hiccups/ HICCUPS	01OCT2013 /69	04OCT2013 /9	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
303-0007/50 /M/A2/Y	Gastrointestinal disorders/ Ascites/ ASCITES	27SEP2013 /65	18OCT2013 /23	C	1	0	1	5	1
304-0001/54 /M/A2/N	Immune system disorders/ Hypersensitivity/ ALLERGY REACTION(UNKNOWN REASON SUSPECT DUE TO ANTIBIOTICS).	20NOV2012 /14	26NOV2012 /-8	C	1	0	1	5	1
	Immune system disorders/ Hypersensitivity/ ALLERGY REACTION-SUSPECTED TO BE CAUSED BY ANTIBIOTICS NEVER CONFIRMED	27NOV2012 /21	12DEC2012 /8	I	1	1	1	5	3
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	07JAN2013 /62	08FEB2013 /66	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
304-0001/54 /M/A2/N	Gastrointestinal disorders/ Diarrhoea/ WATER DIARRHEA	02JAN2013 /57	06JAN2013 /33	C	1	1	1	5	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	07JAN2013 /62	08FEB2013 /66	C	1	0	1	5	2
	Metabolism and nutrition disorders/ Cachexia/ CANCER ANOREXIA-CACHEXIA SYNDROME	19DEC2012 /43	08FEB2013 /66	C	1	1	1	5	3
	Gastrointestinal disorders/ Nausea/ NAUSEA	06DEC2012 /30	08FEB2013 /66	I	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
304-0001/54 /M/A2/N	Skin and subcutaneous tissue disorders/ Pruritus/ LOWER LIMB PRURITUS	20NOV2012 /14	06DEC2012 /2	I	1	1	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	13NOV2012 /7	08FEB2013 /66	C	1	0	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	20NOV2012 /14	20NOV2012 /-14	C	1	1	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ OVERALL SKIN ITCHY	27NOV2012 /21	11DEC2012 /7	C	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
304-0001/54 /M/A2/N	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	20DEC2012 /44	08FEB2013 /66	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	13NOV2012 /7	18DEC2012 /14	C	1	0	1	5	2
	Infections and infestations/ Infection/ INFECTION	11DEC2012 /35	09JAN2013 /36	C	1	1	1	5[Unkown Source Of Infection.]	3
	Infections and infestations/ Infection/ INFECTION	20NOV2012 /14	06DEC2012 /2	C	1	1	1	5[CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
304-0001/54 /M/A2/N	Gastrointestinal disorders/ Vomiting/ VOMITING	23NOV2012 /17	05DEC2012 /1	I	1	1	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	06DEC2012 /30	08FEB2013 /66	I	1	1	1	5	2
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	07JAN2013 /62	08FEB2013 /66	C	1	0	1	5	2
304-0005/58 /M/A2/N	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATRENIA	17JUN2013 /12	21JUN2013 /-5	I	1	0	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
304-0005/58 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	29JUN2013 /24	05JUL2013 /9	I	1	3	1	5	3
	Gastrointestinal disorders/ Gastric varices/ GASTRIC VARICES	27JUN2013 /22	05JUL2013 /9	C	1	0	1	5	1
	General disorders and administration site conditions/ Oedema/ BILATERAL LEG PITTING EDEMA	24JUN2013 /19	27JUN2013 /1	C	1	1	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	05JUN2013 /0	05JUL2013 /9	I	1	3	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
304-0005/58 /M/A2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	26JUN2013 /21	29JUN2013 /3	I	1	1	1	5	1
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Tumour haemorrhage/ DUODENAL TUMOR BLEEDING	25JUN2013 /20	05JUL2013 /9	I	1	1	1	5	2
	Injury, poisoning and procedural complications/ Humerus fracture/ RIGHT HUMERAL SHAFT FRACTURE	30JUN2013 /25	05JUL2013 /9	C	1	3	1	5[Right Humeral Shaft Fracture]	3
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Hepatocellular carcinoma/ WORSENING OF HCC	24JUN2013 /19	05JUL2013 /9	I	4	1	1	5[PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
304-0005/58 /M/A2/N	Gastrointestinal disorders/ Oesophageal varices haemorrhage/ ESOPHAGEAL VARICEAL BLEEDING	17JUN2013 /12	21JUN2013 /-5	I	1	1	1	5 [CD]	3
305-0002/57 /M/A2/N	Gastrointestinal disorders/ Abdominal pain upper/ GASTRIC DISCOMFORTABLE	20FEB2012 /6	02MAR2012 /17	C	1	1	1	5	1
	Nervous system disorders/ Lethargy/ LETHARGY	25FEB2012 /11	11MAR2012 /26	C	1	1	1	5	1
	Nervous system disorders/ Generalised tonic-clonic seizure/ GENERALIZED TONIC-CLONIC SEIZURE	14FEB2012 /0	14FEB2012 /0	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0002/57 /M/A2/N	Nervous system disorders/ Haemorrhage intracranial/ INTRACRANIAL HEMORRHAGE	14FEB2012 /0	01MAR2012 /16	C	2	1	3 /21FEB2012 /Unknown	5[PD]	3
	Nervous system disorders/ Haemorrhage intracranial/ INTRACRANIAL HEMORRHAGE	02MAR2012 /17	17MAR2012 /32	C	1	2	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	16FEB2012 /2	16MAR2012 /31	I	1	1	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	20FEB2012 /6	20FEB2012 /6	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0002/57 /M/A2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	17FEB2012 /3	17FEB2012 /3	I	1	1	1	5	1
305-0003/50 /M/A2/N	Investigations/ International normalised ratio increased/ INR INCREASED	01JUN2012 /107	15JUN2012 /-42	C	1	0	1	5	2
	General disorders and administration site conditions/ Non-cardiac chest pain/ RIGHT CHEST PAIN( NON CARDIAC CHEST PAIN )	29JUN2012 /135	19JUL2012 /-8	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ MILD SHORT OF BREATH	16JUN2012 /122	05JUL2012 /-22	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0003/50 /M/A2/N	General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE REACTION (ITCHING)	18MAY2012 /93	17AUG2012 /21	C	1	1	1	3	1
	General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE REACTION (ITCHING)	22MAR2012 /36	26APR2012 /-92	C	1	1	1	3	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	13MAR2012 /27	15MAR2012 /-134	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	04MAY2012 /79	27JUL2012 /0	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0003/50 /M/A2/N	Gastrointestinal disorders/ Vomiting/ VOMITING	13MAR2012 /27	15MAR2012 /-134	I	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH (WHOLE BODY)	09MAR2012 /23	22MAR2012 /-127	I	1	1	1	3	2
	Nervous system disorders/ Dysaesthesia/ DYSESTHESIA	02MAR2012 /16	09MAR2012 /-140	I	1	0	1	5	1
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	06APR2012 /51	20APR2012 /-98	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0003/50 /M/A2/N	Skin and subcutaneous tissue disorders/ Skin discomfort/ SKIN DISCOMFORT	24AUG2012 /191	07AUG2013 /376	C	1	0	1	5	1
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	18MAY2012 /93	01JUN2012 /-56	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Lung infiltration/ LUNG INFILTRATION	29JUN2012 /135	07AUG2013 /376	C	1	1	1	5	2
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	23MAR2012 /37	04MAY2012 /-84	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0003/50 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Dysphonia/ HOARSENESS	19AUG2012 /186	07AUG2013 /376	C	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRISIS	24AUG2012 /191	07AUG2013 /376	C	1	1	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	19AUG2012 /186	19AUG2012 /23	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ HEMOPTYSIS	11AUG2012 /178	13AUG2012 /17	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0003/50 /M/A2/N	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	13JUL2012 /149	27JUL2012 /0	C	1	1	1	3	1
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	22FEB2012 /7	30MAR2012 /-119	C	1	1	1	3	1
305-0005/48 /M/A2/N	Gastrointestinal disorders/ Ascites/ ASCITES	15MAR2012 /23	09MAY2012 /55	C	1	1	1	5	2
305-0006/65 /M/A2/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	05APR2012 /28	09MAY2012 /-98	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0006/65 /M/A2/Y	General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE REACTION(ITCHING))	02MAY2012 /55	22AUG2012 /7	C	1	1	1	3	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	22AUG2012 /167	28AUG2012 /13	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ HEMOPTYSIS	27JUN2012 /111	22OCT2012 /68	I	1	0	1	5	1
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	27AUG2012 /172	22OCT2012 /68	C	1	2	1	5 [PD]	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0006/65 /M/A2/Y	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	15AUG2012 /160	27AUG2012 /12	C	1	0	1	5	2
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	25APR2012 /48	08MAY2012 /-99	C	1	0	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THOART	18APR2012 /41	25APR2012 /-112	C	1	1	1	5	1
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	07APR2012 /30	25APR2012 /-112	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0006/65 /M/A2/Y	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	07APR2012 /30	25APR2012 /-112	C	1	0	1	5	1
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	30MAR2012 /22	06APR2012 /-131	C	2	0	1	5	3
	Nervous system disorders/ Headache/ HEADACHE	21MAR2012 /13	28MAR2012 /-140	I	1	1	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	30MAR2012 /22	09APR2012 /-128	I	1	1	3 /03APR2012 /11APR2012	5[CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0006/65 /M/A2/Y	General disorders and administration site conditions/ Fatigue/ FATIGUE	21MAR2012 /13	25JUL2012 /-21	I	1	0	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ HEMOPTYSIS	28MAR2012 /20	06APR2012 /-131	C	1	1	1	5	2
	Infections and infestations/ Pneumonia/ PNEUMONIA	30MAR2012 /22	07APR2012 /-130	C	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	30MAR2012 /22	08APR2012 /-129	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0006/65 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	08MAR2012 /0	22OCT2012 /68	C	1	1	1	5	2
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	30MAR2012 /22	06APR2012 /-131	C	2	0	1	5	3
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	30MAR2012 /22	05APR2012 /-132	I	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ HEMOPTYSIS	25APR2012 /48	30MAY2012 /-77	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0006/65 /M/A2/Y	Nervous system disorders/ Headache/ HEADACHE	02APR2012 /25	05APR2012 /-132	I	1	1	1	5	1
305-0009/45 /F/A2/N	Injury, poisoning and procedural complications/ Contusion/ BRUISING	11JUL2012 /91	25JUL2012 /-56	C	1	0	1	5	1
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	01MAY2012 /20	14MAY2012 /-128	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Hypercalcaemia/ HYPERCALCEMIA	22AUG2012 /133	17OCT2012 /28	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0009/45 /F/A2/N	Cardiac disorders/ Sinus tachycardia/ SINUS TACHYCARDIA	11APR2012 /0	15JUL2014 /664	C	1	0	1	5	1
	Hepatobiliary disorders/ Hepatomegaly/ HEPATOMEGALY	18APR2012 /7	26SEP2012 /7	C	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT PAIN	08SEP2012 /150	08SEP2012 /-11	I	1	1	1	5	3
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	05SEP2012 /147	19SEP2012 /0	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0009/45 /F/A2/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	31MAY2012 /50	07SEP2012 /-12	I	1	1	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	16AUG2012 /127	15JUL2014 /664	I	1	0	1	3	1
	Metabolism and nutrition disorders/ Hypercalcaemia/ HYPERCALCEMIA	13JUN2012 /63	21AUG2012 /-29	C	1	0	1	5	1
	General disorders and administration site conditions/ Injection site pain/ INJECTION SITE REACTION (TENDERNESS)	06JUN2012 /56	09OCT2012 /20	I	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0009/45 /F/A2/N	General disorders and administration site conditions/ Injection site pain/ INJECTION SITE REACTION (TENDERNESS)	09MAY2012 /28	05JUN2012 /-106	I	1	1	1	3	2
	Blood and lymphatic system disorders/ Leukopenia/ LEUCOPENIA	01MAY2012 /20	15MAY2012 /-127	C	1	0	1	5	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	29APR2012 /18	01MAY2012 /-141	I	1	1	1	5	1
	Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	18APR2012 /7	01MAY2012 /-141	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0009/45 /F/A2/N	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	01MAY2012 /20	06JUN2012 /-105	I	1	1	1	5	1
	Skin and subcutaneous tissue disorders/ Pigmentation disorder/ SKIN PIGMENTATION	17OCT2012 /189	15JUL2014 /664	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	01MAY2012 /20	14MAY2012 /-128	C	1	1	1	5	2
305-0010/64 /F/A2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	13JUL2012 /86	13JUL2012 /9	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0010/64 /F/A2/N	Gastrointestinal disorders/ Abdominal pain upper/ LEFT UPPER QUADRANT PAIN	16JUL2012 /89	06AUG2012 /33	C	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	07AUG2012 /111	20AUG2012 /47	C	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ LOWER EXTREMITY SORENESS	13JUN2012 /56	25JUN2012 /-9	I	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	11JUL2012 /84	16JUL2012 /12	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0010/64 /F/A2/N	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LOWER LIMBS PITTING EDEMA	11JUL2012 /84	14JUL2012 /10	C	1	1	1	5	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	08MAY2012 /20	22MAY2012 /-43	I	1	0	1	4	1
	General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE REACTION (ITCHING)	08MAY2012 /20	03JUL2012 /-1	C	1	1	1	3	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	25APR2012 /7	07MAY2012 /-58	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0010/64 /F/A2/N	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	24APR2012 /6	07MAY2012 /-58	C	1	0	1	3	1
	Nervous system disorders/ Dizziness/ DIZZINESS	18APR2012 /0	11JUL2012 /7	I	1	0	1	3	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	23MAY2012 /35	11JUN2012 /-23	C	1	1	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ LEG EDEMA	27JUN2012 /70	10JUL2012 /6	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0010/64 /F/A2/N	Gastrointestinal disorders/ Vomiting/ VOMITING	19APR2012 /1	20APR2012 /-75	I	1	0	1	3	1
	Investigations/ Weight increased/ WEIGHT GAIN	04JUL2012 /77	07JUL2012 /3	C	1	0	1	5	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	20JUN2012 /63	04JUL2012 /0	C	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	12JUL2012 /85	14JUL2012 /10	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0010/64 /F/A2/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	06JUN2012 /49	12JUN2012 /-22	I	1	0	1	5	1
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	01MAY2012 /13	14MAY2012 /-51	C	1	1	1	3	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	12JUL2012 /85	13JUL2012 /9	C	1	0	1	5	1
305-0011/68 /M/A2/N	General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE REACTION (ITCHING)	11MAY2012 /14	20JUL2012 /-7	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0011/68 /M/A2/N	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	08JUN2012 /42	12JUL2012 /-15	I	1	0	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	04MAY2012 /7	31MAY2012 /-57	I	1	0	1	5	1
	Infections and infestations/ Biliary tract infection/ BILIARY TRACT INFECTION	10AUG2012 /105	26NOV2012 /122	C	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	10AUG2012 /105	26NOV2012 /122	C	1	0	1	5[The Subject Arrange Percutaneou s Transhepati c Cholangiodr ainage On 17 Aug 2012. Family Ask For Transferred To Local Hospital Near Home. Discharged Him On 24 Aug 2012.]	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0011/68 /M/A2/N	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	27JUL2012 /91	09AUG2012 /13	C	1	0	3 /03AUG2012 /Unknown	5	2
	Gastrointestinal disorders/ Gastrointestinal pain/ GASTROINTESTINAL PAIN	27JUL2012 /91	11AUG2012 /15	I	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Flank pain/ RIGHT FLANK SORENESS	21JUL2012 /85	02AUG2012 /6	C	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	26JUN2012 /60	12JUL2012 /-15	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0011/68 /M/A2/N	General disorders and administration site conditions/ Non-cardiac chest pain/ NON-CARDIAC CHEST PAIN	26JUN2012 /60	26JUL2012 /-1	I	1	0	1	5	1
	Investigations/ Weight decreased/ WEIGHT LOSS	15JUN2012 /49	26NOV2012 /122	C	1	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	21JUL2012 /85	27JUL2012 /0	C	1	0	1	3	1
	Gastrointestinal disorders/ Abdominal pain upper/ MILD EPIGASTRALGIA	08JUN2012 /42	25JUN2012 /-32	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0011/68 /M/A2/N	General disorders and administration site conditions/ Chills/ CHILLS	18MAY2012 /21	31MAY2012 /-57	I	1	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	18MAY2012 /21	31MAY2012 /-57	C	1	0	1	3	1
	Renal and urinary disorders/ Nocturia/ NOCTURIA	04MAY2012 /7	17MAY2012 /-71	I	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	25MAY2012 /28	07JUN2012 /-50	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0011/68 /M/A2/N	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	20JUL2012 /84	02AUG2012 /6	I	1	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	10AUG2012 /105	11AUG2012 /15	I	1	1	1	5	1
	Investigations/ Prothrombin time prolonged/ PROTHROMBIN TIME PROLONG	10AUG2012 /105	26NOV2012 /122	C	1	2	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	28JUL2012 /92	26NOV2012 /122	C	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0011/68 /M/A2/N	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	15JUN2012 /49	25JUN2012 /-32	C	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHROSIS	27APR2012 /0	26NOV2012 /122	C	1	0	1	5	1
305-0012/62 /F/A2/N	Renal and urinary disorders/ Pollakiuria/ URINE FREQUENCY	08DEC2012 /218	04JAN2013 /0	I	1	0	1	5	1
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	01FEB2013 /273	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0012/62 /F/A2/N	Metabolism and nutrition disorders/ Hypocalcaemia/ HYPOCALCEMIA	01FEB2013 /273	Unknown/NA	C	6	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	07DEC2012 /217	14DEC2012 /-21	I	1	0	1	5	1
	Metabolism and nutrition disorders/ Hypocalcaemia/ HYPOCALCEMIA	21DEC2012 /231	04JAN2013 /0	C	1	0	1	5	1
	Gastrointestinal disorders/ Stomatitis/ ORAL MUCOSITIS	24NOV2012 /204	07DEC2012 /-28	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0012/62 /F/A2/N	Musculoskeletal and connective tissue disorders/ Pain in extremity/ LOW LEG OF SORENESS	10NOV2012 /190	23NOV2012 /-42	I	1	0	1	5	1
	Vascular disorders/ Hypotension/ HYPOTENSION	22JUN2012 /49	06JUL2012 /-182	C	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	24AUG2012 /112	14SEP2012 /-112	C	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Back pain/ SORENESS OF BACK	17NOV2012 /197	07DEC2012 /-28	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0012/62 /F/A2/N	Nervous system disorders/ Hypoaesthesia/ EXT NUMBNESS	04AUG2012 /92	14SEP2012 /-112	C	1	1	1	5	1
	Gastrointestinal disorders/ Dry mouth/ DUY MOUTH	22DEC2012 /232	01FEB2013 /28	C	1	0	1	5	1
	Gastrointestinal disorders/ Stomatitis/ ORAL MUCOSITIS	22DEC2012 /232	01FEB2013 /28	C	1	1	1	3	1
	Gastrointestinal disorders/ Cheilitis/ CHEILITIS	22DEC2012 /232	04JAN2013 /0	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0012/62 /F/A2/N	Musculoskeletal and connective tissue disorders/ Neck pain/ SORENESS OF NECK	17NOV2012 /197	07DEC2012 /-28	I	1	1	1	5	1
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	26OCT2012 /175	21DEC2012 /-14	C	1	0	1	5	1
	Gastrointestinal disorders/ Cheilitis/ CHEILITIS	13OCT2012 /162	23NOV2012 /-42	C	1	0	1	5	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	29SEP2012 /148	09NOV2012 /-56	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0012/62 /F/A2/N	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	21SEP2012 /140	05OCT2012 /-91	I	1	1	1	5	1
	Eye disorders/ Conjunctival haemorrhage/ LEFT SUBCONJUNCTIVAL HEMORRHAGE	22SEP2012 /141	05OCT2012 /-91	C	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT PAIN	15SEP2012 /134	28SEP2012 /-98	I	1	0	1	5	2
	Psychiatric disorders/ Insomnia/ INSOMNIA	08SEP2012 /127	28SEP2012 /-98	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0012/62 /F/A2/N	Metabolism and nutrition disorders/ Hypocalcaemia/ HYPOCALCEMIA	20JUL2012 /77	28SEP2012 /-98	C	1	0	1	5	1
	Gastrointestinal disorders/ Cheilitis/ CHEILITIS	06JUL2012 /63	20JUL2012 /-168	C	1	0	1	5	1
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	06JUL2012 /63	12OCT2012 /-84	C	1	0	1	3	1
	Nervous system disorders/ Headache/ HEADACHE	29JUN2012 /56	27JUL2012 /-161	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0012/62 /F/A2/N	Nervous system disorders/ Dizziness/ DIZZINESS	29JUN2012 /56	17AUG2012 /-140	I	1	1	1	5	1
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	22JUN2012 /49	06JUL2012 /-182	C	1	0	1	5	1
	Nervous system disorders/ Hypoaesthesia/ EXT NUMBNESS	15JUN2012 /42	13JUL2012 /-175	C	1	1	1	5	1
	General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE REACTION (ITCHING) (RIGHT ARM)	02JUN2012 /29	24AUG2012 /-133	I	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0012/62 /F/A2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	01JUN2012 /28	15JUN2012 /-203	I	1	0	1	5	1
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	25MAY2012 /21	22JUN2012 /-196	C	1	0	1	5	1
	Nervous system disorders/ Dizziness/ DIZZINESS	25MAY2012 /21	15JUN2012 /-203	C	1	1	1	3	1
	Metabolism and nutrition disorders/ Hypocalcaemia/ HYPOCALCEMIA	22JUN2012 /49	06JUL2012 /-182	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0012/62 /F/A2/N	Eye disorders/ Ocular hyperaemia/ RED EYE	19MAY2012 /15	01JUN2012 /-217	I	1	0	1	5	1
	General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE REACTION(ITCHING) (RIGHT ARM)	19MAY2012 /15	01JUN2012 /-217	I	1	0	1	3	1
	Metabolism and nutrition disorders/ Hypocalcaemia/ HYPOCALCEMIA	11MAY2012 /7	24MAY2012 /-225	C	1	0	1	5	2
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	11MAY2012 /7	24MAY2012 /-225	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0012/62 /F/A2/N	Gastrointestinal disorders/ Abdominal distension/ MILD ABDOMINAL DISTENSION	25MAY2012 /21	15JUN2012 /-203	C	1	0	1	5	1
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	11MAY2012 /7	22JUN2012 /-196	C	1	0	1	4	1
	General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE REACTION(ITCHING) (RIGHT ARM)	04MAY2012 /0	18MAY2012 /-231	I	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	22SEP2012 /141	05OCT2012 /-91	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0012/62 /F/A2/N	Eye disorders/ Ocular hyperaemia/ RED EYES	04MAY2012 /0	18MAY2012 /-231	C	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	13OCT2012 /162	09NOV2012 /-56	I	1	0	1	5	1
	Nervous system disorders/ Dizziness/ DIZZINESS	08SEP2012 /127	26OCT2012 /-70	I	1	1	1	5	1
305-0014/61 /F/A2/N	Respiratory, thoracic and mediastinal disorders/ Pulmonary mass/ LUNG NODULES	14AUG2012 /35	09MAR2013 /172	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0014/61 /F/A2/N	Musculoskeletal and connective tissue disorders/ Back pain/ RIGHT BACK PAIN	09OCT2012 /91	09MAR2013 /172	I	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ CHEST WALL PAIN	21AUG2012 /42	09MAR2013 /172	I	1	0	1	5	1
	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	24JUL2012 /14	07AUG2012 /-42	C	1	1	1	5	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	10JUL2012 /0	09MAR2013 /172	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0019/35 /M/A2/Y	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	30OCT2012 /49	13NOV2012 /28	C	1	0	1	4	1
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	23OCT2012 /42	30OCT2012 /14	C	1	0	3 /23OCT2012 /Unknown	4	2
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	23OCT2012 /42	13NOV2012 /28	C	1	1	1	4	1
	Gastrointestinal disorders/ Ascites/ ASCITES	23OCT2012 /42	13NOV2012 /28	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0019/35 /M/A2/Y	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	16OCT2012 /35	22OCT2012 /6	C	1	1	1	4	2
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	16OCT2012 /35	13NOV2012 /28	C	1	0	1	4	2
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	02OCT2012 /21	08OCT2012 /-8	C	1	1	1	4	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	25SEP2012 /14	16OCT2012 /0	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0019/35 /M/A2/Y	Gastrointestinal disorders/ Upper gastrointestinal haemorrhage/ UPPER GASTROINTESTINAL HEMORRHAGE	08NOV2012 /58	13NOV2012 /28	C	4	1	1	5 [PD]	4
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	30OCT2012 /49	13NOV2012 /28	C	1	1	2	4	3
	General disorders and administration site conditions/ Fatigue/ FATIGUE	23OCT2012 /42	13NOV2012 /28	C	1	0	1	5	1
305-0023/54 /M/A2/N	Infections and infestations/ Gastroenteritis/ ACUTE GASTROENTERITIS	06MAY2013 /118	10MAY2013 /3	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0023/54 /M/A2/N	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIGHT SHOULDER PAIN	12MAR2013 /63	23APR2013 /-14	I	1	1	1	4	1
	Gastrointestinal disorders/ Mouth ulceration/ ORAL ULCER	22JAN2013 /14	29JAN2013 /-98	C	1	1	1	4	1
	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN ITCHY	19FEB2013 /42	12MAR2013 /-56	I	1	1	1	4	1
305-0025/77 /F/A2/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	14APR2013 /82	Unknown/NA	I	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0025/77 /F/A2/N	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	27APR2013 /95	Unknown/NA	C	6	3	1	5	3
	General disorders and administration site conditions/ Fatigue/ FATIGUE	29APR2013 /97	Unknown/NA	C	6	0	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	29APR2013 /97	29APR2013 /27	C	1	0	1	5	1
	Renal and urinary disorders/ Pollakiuria/ URINE FREQUENCY	20FEB2013 /29	24APR2013 /22	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0025/77 /F/A2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	07APR2013 /75	08APR2013 /6	C	1	0	1	5	1
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	29APR2013 /97	02AUG2013 /122	C	4	1	1	5 [CD]	5
	Nervous system disorders/ Depressed level of consciousness/ CONSCIOUSNESS LEVEL OF DETERIORATED	12APR2013 /80	18APR2013 /16	C	1	1	2	5	2
	Renal and urinary disorders/ Urinary incontinence/ URINARY INCONTINENCE	10APR2013 /78	10APR2013 /8	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0025/77 /F/A2/N	Nervous system disorders/ Tremor/ WORESNING TREMOR	26MAR2013 /63	07APR2013 /5	I	1	0	1	5	2
	Nervous system disorders/ Depressed level of consciousness/ CONSCIOUSNESS LEVEL OF DETERIORATED	02APR2013 /70	11APR2013 /9	C	1	1	3 /09APR2013 /11APR2013	5[CD]	3
	General disorders and administration site conditions/ Pyrexia/ FEVER	18MAR2013 /55	18MAR2013 /-15	I	1	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	13MAR2013 /50	25MAR2013 /-8	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0025/77 /F/A2/N	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	13MAR2013 /50	01APR2013 /-1	C	1	1	1	5	1
	Nervous system disorders/ Tremor/ TREMOR	27FEB2013 /36	26MAR2013 /-7	I	1	0	1	5	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	06FEB2013 /15	Unknown/NA	C	6	1	1	5	1
	Nervous system disorders/ Depressed level of consciousness/ DEPRESSED LEVEL OF CONSCIOUSNESS	30JAN2013 /8	12MAR2013 /-21	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0025/77 /F/A2/N	Renal and urinary disorders/ Pollakiuria/ URINARY FREQUENCY	30JAN2013 /8	18FEB2013 /-43	C	1	1	1	5	2
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	15FEB2013 /24	26MAR2013 /-7	C	1	0	1	5	1
	Investigations/ White blood cell count decreased/ WORSENING WHITE BLOOD CELL DECREASED	29JAN2013 /7	14FEB2013 /-47	C	2	0	1	5	2
	Renal and urinary disorders/ Urinary retention/ URINARY RETENTION	29APR2013 /97	29APR2013 /27	I	1	3	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0025/77 /F/A2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	06FEB2013 /15	26FEB2013 /-35	C	1	0	1	5	1
	Eye disorders/ Eye discharge/ DISCHARGE OVER RIGHT EYE	08APR2013 /76	17APR2013 /15	C	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENTION	07APR2013 /75	08APR2013 /6	I	1	0	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	26MAR2013 /63	01APR2013 /-1	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0026/45 /M/A2/Y	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	28MAY2013 /91	02JUN2013 /-72	I	1	2	1	5	3
	Gastrointestinal disorders/ Gastrointestinal haemorrhage/ GASTROINTESTINAL HEMORRHAGE	29MAY2013 /92	19JUN2013 /-55	C	1	3	3 /04JUN2013 /21JUN2013	5 [CD]	4
	Skin and subcutaneous tissue disorders/ Rash pruritic/ PRURITUS (CHEST SKIN RASH WITH ITCHING)	08MAY2013 /71	20MAY2013 /-85	C	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	08MAY2013 /71	20MAY2013 /-85	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0026/45 /M/A2/Y	Psychiatric disorders/ Insomnia/ INSOMNIA	24APR2013 /57	20DEC2013 /129	I	1	1	1	5	1
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	16APR2013 /49	29APR2013 /-106	C	1	0	1	3	2
	Investigations/ Neutrophil count decreased/ NEUTROPHIL COUNT DECREASED	02APR2013 /35	08APR2013 /-127	C	1	0	1	3	2
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	17APR2013 /50	27MAY2013 /-78	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0026/45 /M/A2/Y	Investigations/ Neutrophil count decreased/ NEUTROPHIL COUNT DECREASED	19MAR2013 /21	01APR2013 /-134	C	1	0	1	3	3
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	19MAR2013 /21	08APR2013 /-127	C	1	0	3 /27MAR2013 /09APR2013	3	3
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	05MAR2013 /7	18MAR2013 /-148	C	1	0	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	04MAR2013 /6	05MAR2013 /-161	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0026/45 /M/A2/Y	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	20MAR2013 /22	01APR2013 /-134	C	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	18MAR2013 /20	19MAR2013 /-147	I	1	0	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	04MAR2013 /6	27MAY2013 /-78	I	1	1	1	3	1
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	26MAR2013 /28	01APR2013 /-134	C	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0026/45 /M/A2/Y	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	06MAR2013 /8	01APR2013 /-134	C	1	0	1	3	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	19MAR2013 /21	25MAR2013 /-141	C	1	0	1	3	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	26MAR2013 /28	13MAY2013 /-92	C	1	0	1	3	3
	Gastrointestinal disorders/ Abdominal pain/ LEFT ABDOMINAL PAIN	22MAY2013 /85	29MAY2013 /-76	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0026/45 /M/A2/Y	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	28MAY2013 /91	20DEC2013 /129	I	1	1	1	5	3
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	14MAY2013 /77	27MAY2013 /-78	C	1	0	1	5	2
	Gastrointestinal disorders/ Abdominal pain/ PERI-UMBILICAL PAIN	08MAY2013 /71	20MAY2013 /-85	I	1	0	1	5	1
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	02APR2013 /35	15APR2013 /-120	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0026/45 /M/A2/Y	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	30APR2013 /63	13MAY2013 /-92	C	1	0	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORETHOAT	02APR2013 /35	09APR2013 /-126	C	1	0	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	09JUL2013 /133	15JUL2013 /-29	C	1	2	1	5	3
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	03JUN2013 /97	13JUN2013 /-61	C	1	2	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0026/45 /M/A2/Y	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	25JUN2013 /119	08JUL2013 /-36	C	1	0	1	5	2
	Reproductive system and breast disorders/ Oedema genital/ GENITAL EDEMA	01JUN2013 /95	07JUN2013 /-67	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	11JUN2013 /105	24JUN2013 /-50	C	1	0	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	11JUN2013 /105	08JUL2013 /-36	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0026/45 /M/A2/Y	Investigations/ International normalised ratio increased/ INR INCREASED	29MAY2013 /92	24JUN2013 /-50	C	1	2	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	02JUN2013 /96	15JUN2013 /-59	I	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ RIGHT PLEURAL EFFUSION	13AUG2013 /168	20DEC2013 /129	C	1	0	1	5	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	07AUG2013 /162	20DEC2013 /129	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0026/45 /M/A2/Y	Vascular disorders/ Deep vein thrombosis/ DEEP VEIN THROMBOSIS LOW EXTREMETIES	11JUN2013 /105	20DEC2013 /129	C	1	0	1	5	1
	Gastrointestinal disorders/ Gastric varices/ GASTRIC VARICES	30MAY2013 /93	20DEC2013 /129	C	1	0	1	5	1
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	28MAY2013 /91	29MAY2013 /-76	C	1	0	1	5	1
	Gastrointestinal disorders/ Varices oesophageal/ ESOPHAGEAL VARICES	30MAY2013 /93	20DEC2013 /129	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0026/45 /M/A2/Y	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	03JUN2013 /97	11JUN2013 /-63	C	1	1	1	5	3
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	14MAY2013 /77	27MAY2013 /-78	C	1	0	1	5	2
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	30APR2013 /63	14JUN2013 /-60	C	1	0	1	5	1
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	11JUN2013 /105	12JUL2013 /-32	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0026/45 /M/A2/Y	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	01AUG2013 /156	20DEC2013 /129	C	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Erythema/ RED BUTTOCKS	04AUG2013 /159	05AUG2013 /-8	C	1	0	1	5	1
	Gastrointestinal disorders/ Stomatitis/ MUCOSITIS ORAL	02AUG2013 /157	05AUG2013 /-8	I	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	02AUG2013 /157	02AUG2013 /-11	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0026/45 /M/A2/Y	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	02AUG2013 /157	02AUG2013 /-11	C	1	2	1	5	2
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	08JUN2013 /102	10JUL2013 /-34	C	1	0	1	5	1
	Investigations/ International normalised ratio increased/ INR INCREASED	01AUG2013 /156	20DEC2013 /129	C	1	0	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	01AUG2013 /156	01AUG2013 /-12	C	1	2	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0026/45 /M/A2/Y	Gastrointestinal disorders/ Gastric varices haemorrhage/ GASTRIC VARICOSE BLEEDING	01AUG2013 /156	05AUG2013 /-8	I	1	3	1	5[CD]	3
	General disorders and administration site conditions/ Fatigue/ FATIGUE	01AUG2013 /156	05AUG2013 /-8	C	1	0	1	5	2
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	06JUN2013 /100	10JUN2013 /-64	C	1	0	1	5	1
	Immune system disorders/ Hypersensitivity/ ALLERGIC REACTION	02JUN2013 /96	02JUN2013 /-72	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0026/45 /M/A2/Y	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	23JUL2013 /147	31JUL2013 /-13	C	1	0	1	5	1
	Gastrointestinal disorders/ Ascites/ ASCITES	21MAY2013 /84	20DEC2013 /129	I	1	1	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	09JUL2013 /133	20DEC2013 /129	C	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN ITCHING	17JUL2013 /141	20DEC2013 /129	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0026/45 /M/A2/Y	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	16JUL2013 /140	31JUL2013 /-13	C	1	2	1	5	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	07JUN2013 /101	08JUN2013 /-66	I	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	12JUL2013 /136	29JUL2013 /-15	I	1	0	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	12JUL2013 /136	29JUL2013 /-15	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0026/45 /M/A2/Y	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	12JUL2013 /136	22JUL2013 /-22	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	03JUN2013 /97	05JUN2013 /-69	C	1	1	1	5	2
305-0028/73 /F/A2/N	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT PAIN	04APR2013 /20	16APR2013 /-43	I	1	0	1	5	1
	General disorders and administration site conditions/ Nodule/ NECK SMALL NODULE	22MAY2013 /68	16JUN2013 /18	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0028/73 /F/A2/N	Respiratory, thoracic and mediastinal disorders/ Wheezing/ WHEEZING	06JUN2013 /83	06JUN2013 /8	I	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Pneumonitis/ BILATERAL OBSTRUCTIVE PNEUMONITIS	14JUN2013 /91	16JUN2013 /18	C	1	3	1	5	3
	Gastrointestinal disorders/ Vomiting/ VOMITING	15JUN2013 /92	16JUN2013 /18	I	1	1	1	5	1
	Nervous system disorders/ Encephalopathy/ ENCEPHALOPATHY	14JUN2013 /91	16JUN2013 /18	C	4	1	1	5 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0028/73 /F/A2/N	Metabolism and nutrition disorders/ Cachexia/ CACHEXIA	24APR2013 /40	16JUN2013 /18	C	1	1	1	5	2
	Investigations/ Weight decreased/ WEIGHT LOSS	08MAY2013 /54	16JUN2013 /18	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	01MAY2013 /47	16JUN2013 /18	C	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	20MAR2013 /5	15MAY2013 /-14	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0028/73 /F/A2/N	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRAGIA	28MAR2013 /13	09APR2013 /-50	I	1	1	1	5	1
305-0030/61 /M/A2/N	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	20MAY2013 /48	26JUN2013 /43	I	1	1	1	4	1
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	06JUN2013 /65	26JUN2013 /43	C	1	0	1	4	3
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	03JUN2013 /62	07JUN2013 /24	I	1	2	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0030/61 /M/A2/N	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	20MAY2013 /48	11JUN2013 /28	C	1	1	1	4	1
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	27MAY2013 /55	31MAY2013 /17	C	1	2	1	4	2
	General disorders and administration site conditions/ Malaise/ MALAISE	20MAY2013 /48	26JUN2013 /43	C	1	0	1	4	1
	Gastrointestinal disorders/ Ascites/ ASCITES	14MAY2013 /42	20MAY2013 /6	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0030/61 /M/A2/N	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	14MAY2013 /42	31MAY2013 /17	C	1	1	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	20MAY2013 /48	02JUN2013 /19	I	1	1	1	4	2
	Gastrointestinal disorders/ Mouth ulceration/ ORAL ULCER	04JUN2013 /63	07JUN2013 /24	C	1	1	1	4	1
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	20MAY2013 /48	23MAY2013 /9	I	1	2	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0030/61 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	17MAY2013 /45	07JUN2013 /24	I	1	0	1	4	1
	Infections and infestations/ Biliary tract infection/ BILIARY TRACT INFECTION	17MAY2013 /45	07JUN2013 /24	C	1	3	2	4[Gall Bladder Stone]	3
	Hepatobiliary disorders/ Cholelithiasis/ GALL BLADDER STONE	17MAY2013 /45	29MAY2013 /15	C	1	2	1	4	1
305-0031/29 /M/A2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	02MAY2013 /30	02MAY2013 /9	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0031/29 /M/A2/N	Nervous system disorders/ Somnolence/ SLEEPY	07MAY2013 /35	08MAY2013 /15	C	1	1	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	13MAY2013 /41	13MAY2013 /20	C	1	2	1	4	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	27APR2013 /25	13MAY2013 /20	I	1	1	1	4	2
	Cardiac disorders/ Sinus tachycardia/ SINUS TACHYCARDIA	16APR2013 /14	13MAY2013 /20	I	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0031/29 /M/A2/N	General disorders and administration site conditions/ Localised oedema/ LOCALIZED EDEMA	13MAY2013 /41	13MAY2013 /20	C	1	1	1	4	1
	General disorders and administration site conditions/ Influenza like illness/ FLU LIKE SYMPTOMS	02MAY2013 /30	03MAY2013 /10	C	1	0	1	4	1
	Vascular disorders/ Shock/ SHOCK	09MAY2013 /37	13MAY2013 /20	C	1	3	1	4	2
	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	06MAY2013 /34	08MAY2013 /15	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0031/29 /M/A2/N	Psychiatric disorders/ Depression/ DEPRESSION	09APR2013 /7	13MAY2013 /20	I	1	1	1	4	1
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	07MAY2013 /35	13MAY2013 /20	I	1	1	1	4	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	09APR2013 /7	26APR2013 /3	C	1	0	1	4	2
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ HCC PROGRESSION	24APR2013 /22	13MAY2013 /20	C	4	2	2	5 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0031/29 /M/A2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	09MAY2013 /37	09MAY2013 /16	C	1	0	1	4	1
305-0034/53 /M/A2/Y	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	10JUL2013 /7	24AUG2013 /24	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	31JUL2013 /28	24AUG2013 /24	C	1	0	1	5	1
	General disorders and administration site conditions/ Chills/ CHILLS	27JUL2013 /24	31JUL2013 /0	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0034/53 /M/A2/Y	General disorders and administration site conditions/ Disease progression/ WORSENING OF HEPATIC CARCINOMA	01AUG2013 /29	24AUG2013 /24	C	4	0	2	5 [PD]	5
	Nervous system disorders/ Dizziness/ DIZZINESS	08AUG2013 /36	24AUG2013 /24	I	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	05AUG2013 /33	24AUG2013 /24	I	1	3	1	5	2
	Psychiatric disorders/ Insomnia/ INSOMNIA	05AUG2013 /33	24AUG2013 /24	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0034/53 /M/A2/Y	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	03AUG2013 /31	24AUG2013 /24	I	1	0	1	5	1
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	01AUG2013 /29	12AUG2013 /12	C	1	0	1	5	2
	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	01AUG2013 /29	24AUG2013 /24	C	1	0	1	5	1
	Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	22JUL2013 /19	24AUG2013 /24	C	1	2	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0034/53 /M/A2/Y	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	01AUG2013 /29	12AUG2013 /12	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	01AUG2013 /29	24AUG2013 /24	C	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Hiccups/ HICCUP	31JUL2013 /28	02AUG2013 /2	I	1	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	01AUG2013 /29	24AUG2013 /24	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0034/53 /M/A2/Y	Musculoskeletal and connective tissue disorders/ Bone pain/ BONE SORENESS	01AUG2013 /29	24AUG2013 /24	I	1	1	1	3	1
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	25JUL2013 /22	24AUG2013 /24	C	1	1	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	27JUL2013 /24	06AUG2013 /6	I	1	1	1	5	2
	General disorders and administration site conditions/ Injection site reaction/ INJECTION SITE REACTION	10JUL2013 /7	01AUG2013 /1	I	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0034/53 /M/A2/Y	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	22JUL2013 /19	31JUL2013 /0	C	1	0	1	5	3
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	22JUL2013 /19	31JUL2013 /0	C	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Purpura/ PURPURA	18JUL2013 /15	20AUG2013 /20	I	1	1	1	5	1
	General disorders and administration site conditions/ Non-cardiac chest pain/ NON-CARDIC CHEST PAIN	11JUL2013 /8	01AUG2013 /1	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0034/53 /M/A2/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	12JUL2013 /9	12JUL2013 /-19	C	1	0	1	5	1
	Gastrointestinal disorders/ Haemorrhoids/ HEMORRHOIDS	04JUL2013 /1	24AUG2013 /24	C	1	1	1	5	1
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	19AUG2013 /47	24AUG2013 /24	C	1	2	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	01AUG2013 /29	24AUG2013 /24	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0034/53 /M/A2/Y	General disorders and administration site conditions/ Chills/ CHILLS	12JUL2013 /9	12JUL2013 /-19	C	1	0	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	01AUG2013 /29	24AUG2013 /24	C	1	0	1	5	1
	Investigations/ International normalised ratio increased/ INR INCREASED	13AUG2013 /41	24AUG2013 /24	C	1	0	1	5	1
	Hepatobiliary disorders/ Jaundice cholestatic/ OBSTRUCTIVE JAUNDICE	13AUG2013 /41	24AUG2013 /24	C	1	3	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0034/53 /M/A2/Y	General disorders and administration site conditions/ Malaise/ MALAISE	13AUG2013 /41	24AUG2013 /24	C	1	0	1	5	2
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	08AUG2013 /36	24AUG2013 /24	I	1	1	1	5	1
305-0036/38 /M/A2/Y	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHY	06DEC2013 /92	06DEC2013 /17	C	1	1	1	4	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	30NOV2013 /86	01DEC2013 /12	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0036/38 /M/A2/Y	General disorders and administration site conditions/ Pain/ GENERALIZED PAIN	02DEC2013 /88	Unknown/NA	I	6	1	1	4	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	02DEC2013 /88	02DEC2013 /13	C	1	1	1	4	1
	Gastrointestinal disorders/ Haemorrhoidal haemorrhage/ HEMORRHOID BLEEDING	01DEC2013 /87	02DEC2013 /13	C	1	1	1	4	1
	Injury, poisoning and procedural complications/ Road traffic accident/ TRAFFIC ACCIDENT	05NOV2013 /61	05NOV2013 /-14	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0036/38 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORT OF BREATH	01DEC2013 /87	07DEC2013 /18	I	1	1	1	4	2
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	30NOV2013 /86	02DEC2013 /13	C	1	1	1	4	1
	Blood and lymphatic system disorders/ Microcytic anaemia/ MICROCYTIC ANEMIA	27NOV2013 /83	09DEC2013 /20	C	1	2	1	4	2
	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	28NOV2013 /84	28NOV2013 /9	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0036/38 /M/A2/Y	Nervous system disorders/ Headache/ HEADACHE	28NOV2013 /84	28NOV2013 /9	C	1	0	1	4	1
	Gastrointestinal disorders/ Duodenal ulcer/ DUODENAL ULCER	29NOV2013 /85	Unknown/NA	C	6	1	1	4	1
	Investigations/ Weight decreased/ WEIGHT LOSS	19NOV2013 /75	Unknown/NA	C	6	0	1	4	1
	Skin and subcutaneous tissue disorders/ Alopecia/ ALOPECIA	17OCT2013 /42	Unknown/NA	C	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0036/38 /M/A2/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	29SEP2013 /24	Unknown/NA	I	6	0	1	4	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	28SEP2013 /23	Unknown/NA	I	6	1	1	4	2
	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN ITCHY	15SEP2013 /10	14NOV2013 /-5	I	1	1	1	3	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	05SEP2013 /0	05SEP2013 /-75	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0036/38 /M/A2/Y	Gastrointestinal disorders/ Gastritis haemorrhagic/ UPPER GASTRITIS BLEEDING	26NOV2013 /82	17DEC2013 /28	I	1	3	1	4 [PD]	3
	Infections and infestations/ Pneumonia/ PNEUMONIA	28NOV2013 /84	Unknown/NA	C	6	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	01DEC2013 /87	13DEC2013 /24	I	1	1	1	4	1
305-0037/50 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	09JAN2014 /77	16JAN2014 /7	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0037/50 /M/A2/Y	General disorders and administration site conditions/ Deformity/ DEFORMED PYLORUS	11FEB2014 /110	24JUN2014 /166	C	1	0	1	4	1
	Gastrointestinal disorders/ Duodenal varices/ DUODENAL VARICES	11FEB2014 /110	24JUN2014 /166	C	1	0	1	4	1
	Gastrointestinal disorders/ Gastritis/ SUPERIFICAL GASTRITIS	11FEB2014 /110	24JUN2014 /166	C	1	0	1	4	1
	Gastrointestinal disorders/ Gastric varices/ GASTRIC VARICES	11FEB2014 /110	24JUN2014 /166	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0037/50 /M/A2/Y	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	09JAN2014 /77	11FEB2014 /33	C	1	2	3 /16JAN2014 /Unknown	4	3
	Gastrointestinal disorders/ Varices oesophageal/ ESOPHAGEAL VARICES	11FEB2014 /110	24JUN2014 /166	C	1	0	1	4	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	09JAN2014 /77	11FEB2014 /33	I	1	1	1	5	1
	Gastrointestinal disorders/ Ascites/ ASCITES	09JAN2014 /77	24JUN2014 /166	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0039/36 /M/A2/Y	Infections and infestations/ Abdominal infection/ ABDOMINAL INFECTION	24DEC2013 /26	26DEC2013 /7	C	1	1	1	4	3
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORT OF BREATH	25DEC2013 /27	26DEC2013 /7	C	1	2	1	4	2
	Gastrointestinal disorders/ Haematemesis/ COFFEE GROUND	24DEC2013 /26	26DEC2013 /7	C	1	3	1	4	2
	Investigations/ Weight decreased/ WEIGHT LOSS	19DEC2013 /21	26DEC2013 /7	C	1	0	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0039/36 /M/A2/Y	General disorders and administration site conditions/ Asthenia/ WEEKNESS	19DEC2013 /21	20DEC2013 /1	C	1	0	1	4	2
	Respiratory, thoracic and mediastinal disorders/ Sputum discoloured/ COUGH YELLOIWHS SPUTUM	12DEC2013 /14	24DEC2013 /5	C	1	1	1	4	2
	Gastrointestinal disorders/ Haemorrhoids/ ANAL HEMORRHOIDS PAIN	05DEC2013 /7	24DEC2013 /5	C	1	1	1	4	2
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	05DEC2013 /7	26DEC2013 /7	C	1	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0039/36 /M/A2/Y	General disorders and administration site conditions/ Asthenia/ WEEKNESS	05DEC2013 /7	18DEC2013 /-1	C	1	0	1	4	1
	Investigations/ Weight decreased/ WEIGHT LOSS	28NOV2013 /0	18DEC2013 /-1	C	1	0	1	5	2
	Nervous system disorders/ Coma hepatic/ HEPATIC COMA	21DEC2013 /23	26DEC2013 /7	C	4	3	1	5 [PD]	5
305-0040/61 /M/A2/N	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	17NOV2013 /2	26JUN2014 /209	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0040/61 /M/A2/N	Nervous system disorders/ Depressed level of consciousness/ DEPRESSED LEVEL OF CONCIOUSNESS	19NOV2013 /4	26JUN2014 /209	I	1	1	1	5	1
	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	17NOV2013 /2	26JUN2014 /209	C	1	1	1	5	2
305-0043/70 /M/A2/N	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	29JUL2014 /28	26AUG2014 /-21	I	1	1	1	4	2
	Musculoskeletal and connective tissue disorders/ Back pain/ RIGHT BACK PAIN	08JUL2014 /7	Unknown/NA	I	6	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0045/65 /M/A2/Y	Gastrointestinal disorders/ Varices oesophageal/ ESOPHAGEAL VARICES	23NOV2014 /37	05DEC2014 /28	C	1	1	1	5	1
	Gastrointestinal disorders/ Oesophageal varices haemorrhage/ ESOPHAGEAL VARICES HEMORRHAGE	23NOV2014 /37	26NOV2014 /19	I	1	3	1	5	3
	Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	23NOV2014 /37	05DEC2014 /28	C	1	0	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	27NOV2014 /41	05DEC2014 /28	C	1	2	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0045/65 /M/A2/Y	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	23NOV2014 /37	05DEC2014 /28	C	1	0	1	5	3
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	20NOV2014 /34	26NOV2014 /19	C	1	0	1	5	1
	Infections and infestations/ Cellulitis/ RIGHT LOWER LEG CELLULITIS	15NOV2014 /29	27NOV2014 /20	C	1	1	1	5 [CD]	3
	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	20NOV2014 /34	26NOV2014 /19	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0045/65 /M/A2/Y	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	20NOV2014 /34	26NOV2014 /19	C	1	2	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	18NOV2014 /32	05DEC2014 /28	I	1	1	1	5	2
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	15NOV2014 /29	05DEC2014 /28	C	1	0	1	5	3
	Musculoskeletal and connective tissue disorders/ Back pain/ BACKACHE	31OCT2014 /14	05DEC2014 /28	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0045/65 /M/A2/Y	Psychiatric disorders/ Insomnia/ INSOMNIA	18NOV2014 /32	05DEC2014 /28	I	1	1	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	17NOV2014 /31	05DEC2014 /28	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	15NOV2014 /29	19NOV2014 /12	C	1	2	1	5	2
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	15NOV2014 /29	22NOV2014 /15	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0045/65 /M/A2/Y	General disorders and administration site conditions/ Fatigue/ FATIGUE	10NOV2014 /24	05DEC2014 /28	C	1	0	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	10NOV2014 /24	16NOV2014 /9	I	1	0	1	5	2
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	07NOV2014 /21	14NOV2014 /7	C	1	0	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	07NOV2014 /21	16NOV2014 /9	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0045/65 /M/A2/Y	Gastrointestinal disorders/ Ascites/ ASCITES	07NOV2014 /21	05DEC2014 /28	C	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	31OCT2014 /14	07NOV2014 /0	I	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ EPIGASTRIC DISTENSION	17OCT2014 /0	05DEC2014 /28	I	1	1	1	5	1
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	24OCT2014 /7	15NOV2014 /8	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0045/65 /M/A2/Y	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	24OCT2014 /7	22NOV2014 /15	C	1	0	1	5	2
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	24OCT2014 /7	07NOV2014 /0	C	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Flank pain/ RIGHT FLANK PAIN	20OCT2014 /3	31OCT2014 /-7	C	1	1	1	5	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	31OCT2014 /14	07NOV2014 /0	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0047/58 /M/A2/N	Renal and urinary disorders/ Urinary retention/ URINARY RETENTION	23JAN2015 /29	28JAN2015 /14	C	1	2	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Hypoxia/ HYPOXEMIA	26JAN2015 /32	28JAN2015 /14	C	1	2	1	5	2
	Gastrointestinal disorders/ Haematemesis/ VOMITING WITH HEMORRHAGE	28JAN2015 /34	28JAN2015 /14	I	1	1	1	5	2
	Gastrointestinal disorders/ Haematemesis/ VOMITING WITH HEMORRHAGE	21JAN2015 /27	21JAN2015 /7	I	1	3	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0047/58 /M/A2/N	Renal and urinary disorders/ Haematuria/ HEMATURIA	24JAN2015 /30	24JAN2015 /10	I	1	1	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	23JAN2015 /29	28JAN2015 /14	I	1	1	1	5	1
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	23JAN2015 /29	28JAN2015 /14	C	1	0	1	5	1
	Nervous system disorders/ Somnolence/ CONSCIOUSNESS DROWSY	23JAN2015 /29	28JAN2015 /14	I	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0047/58 /M/A2/N	Gastrointestinal disorders/ Vomiting/ VOMITING	21JAN2015 /27	28JAN2015 /14	I	1	1	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	21JAN2015 /27	23JAN2015 /9	C	1	2	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	21JAN2015 /27	28JAN2015 /14	C	1	0	1	5	1
	Investigations/ Prothrombin time prolonged/ PROTHROMBIN TIME PROLONG	21JAN2015 /27	28JAN2015 /14	C	1	3	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0047/58 /M/A2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	17JAN2015 /23	28JAN2015 /14	C	1	0	1	5	1
	Nervous system disorders/ Tremor/ HAND TREMOR	16JAN2015 /22	28JAN2015 /14	I	1	0	1	5	1
	Vascular disorders/ Hypertension/ HYPERTENSION	17JAN2015 /23	28JAN2015 /14	I	1	1	3 /23JAN2015 /Unknown	5[CD]	3
	Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHROSIS	31DEC2014 /6	28JAN2015 /14	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0047/58 /M/A2/N	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	17JAN2015 /23	21JAN2015 /7	C	1	0	1	5	2
	Nervous system disorders/ Somnolence/ CONSCIOUSNESS DROWSY	14JAN2015 /20	16JAN2015 /2	I	1	0	1	5	1
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	16JAN2015 /22	28JAN2015 /14	I	4	1	2	5 [CD]	5
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	14JAN2015 /20	16JAN2015 /2	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0047/58 /M/A2/N	General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	14JAN2015 /20	23JAN2015 /9	I	1	0	1	2	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	14JAN2015 /20	28JAN2015 /14	I	1	0	1	5	2
	General disorders and administration site conditions/ Chills/ CHILLS	14JAN2015 /20	17JAN2015 /3	I	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIGHT SCAPULAR PAIN	07JAN2015 /13	28JAN2015 /14	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0047/58 /M/A2/N	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN ITCHING OVER INGUINAL AREA	07JAN2015 /13	28JAN2015 /14	I	1	1	1	3	2
	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT PAIN	31DEC2014 /6	28JAN2015 /14	I	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ LIMB PAIN	19JAN2015 /25	20JAN2015 /6	C	1	0	1	5	1
305-0048/55 /M/A2/Y	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	28APR2015 /63	12MAY2015 /0	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0048/55 /M/A2/Y	Gastrointestinal disorders/ Enterocolitis/ ENTEROCOLITIS	12MAY2015 /77	21MAY2015 /9	C	1	3	1	4 [CD]	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	10MAR2015 /14	17MAR2015 /-56	I	1	1	1	5	1
	Gastrointestinal disorders/ Varices oesophageal/ ESOPHAGEL VARICES	10MAR2015 /14	10MAR2015 /-63	C	1	2	1	5	3
	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN ITCHING	05MAY2015 /70	26MAY2015 /14	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0048/55 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	10MAR2015 /14	31MAR2015 /-42	I	1	1	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	06MAR2015 /10	20MAR2015 /-53	C	1	0	1	4	2
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPEMIA	06MAR2015 /10	03APR2015 /-39	C	1	0	1	4	3
	Blood and lymphatic system disorders/ Leukopenia/ LEUKOCYTOPENIA	06MAR2015 /10	20MAR2015 /-53	C	1	0	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0048/55 /M/A2/Y	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	06MAR2015 /10	03APR2015 /-39	C	1	0	1	4	2
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	28FEB2015 /4	17MAR2015 /-56	C	1	1	3 /05MAR2015 /17MAR2015	5 [PD]	3
	Renal and urinary disorders/ Pollakiuria/ URINARY FREQUENCY	04MAR2015 /8	Unknown/NA	C	6	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	04MAR2015 /8	Unknown/NA	I	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0048/55 /M/A2/Y	Injury, poisoning and procedural complications/ Wound/ WOUND OVER FACE	03MAR2015 /7	Unknown/NA	C	6	0	1	5	1
	Nervous system disorders/ Altered state of consciousness/ CONSCIOUS DISTURBANCE	27FEB2015 /3	01MAR2015 /-72	I	1	1	1	3	1
306-0001/56 /M/A2/Y	Skin and subcutaneous tissue disorders/ Palmar-plantar erythrodysaesthesia syndrome/ PALMAR-PLANTAR ERYTHRODYSESTHESIA SYNDROME	09MAR2012 /21	04MAY2012 /0	C	1	1	1	1	1
	General disorders and administration site conditions/ Pain/ PAIN	20APR2012 /63	22APR2012 /-12	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0001/56 /M/A2/Y	Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEGS SORENESS	06APR2012 /49	04MAY2012 /0	C	1	0	1	5	1
306-0002/73 /M/A2/N	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	08MAY2012 /84	14MAY2012 /20	C	1	1	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	03MAY2012 /79	07MAY2012 /13	C	1	1	1	5	1
	Gastrointestinal disorders/ Varices oesophageal/ ESOPHAGEAL VARICES"(IT'S WORSENING COMPARE WITH MEDICAL HISTORY)	02MAY2012 /78	21AUG2012 /119	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0002/73 /M/A2/N	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	29APR2012 /75	30APR2012 /6	C	1	3	1	5 [CD]	3
	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ CHEST WALL PAIN	30APR2012 /76	21MAY2012 /27	I	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	13MAR2012 /28	19MAR2012 /-36	I	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ CHEST WALL PAIN	27APR2012 /73	29APR2012 /5	I	2	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0002/73 /M/A2/N	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTIC PAIN	25APR2012 /71	30APR2012 /6	I	1	3	1	5	2
	General disorders and administration site conditions/ Injection site pruritus/ ITCHING AT INJECTING SITE	17APR2012 /63	23APR2012 /-1	C	1	1	1	1	1
	Gastrointestinal disorders/ Duodenal ulcer/ DUODENAL ULCER	02MAY2012 /78	21AUG2012 /119	I	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Arthritis/ ARTHRITIS	17APR2012 /63	21AUG2012 /119	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0002/73 /M/A2/N	Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA OVER BILATERAL SHOULDER AND HIPS	06MAR2012 /21	13MAR2012 /-42	C	1	1	1	1	1
	Gastrointestinal disorders/ Stomatitis/ ORAL MUCOSITIS	03APR2012 /49	17APR2012 /-7	C	1	1	1	4	3
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ PAIN IN EXTERMITTY	27MAR2012 /42	10APR2012 /-14	I	1	1	1	4	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	20MAR2012 /35	26MAR2012 /-29	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0002/73 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	06MAR2012 /21	10APR2012 /-14	C	1	1	1	4	1
306-0005/69 /F/A2/N	Investigations/ Alpha 1 foetoprotein increased/ ELEVATION OF AFP LEVEL	16MAR2012 /21	29JUL2012 /100	C	1	0	1	5	2
	Musculoskeletal and connective tissue disorders/ Back pain/ LOWER BACK PAIN	16MAR2012 /21	20APR2012 /0	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	27JUN2012 /124	29JUL2012 /100	C	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0005/69 /F/A2/N	Investigations/ Alanine aminotransferase increased/ INCREASED ALT	02MAR2012 /7	16MAR2012 /-35	C	1	0	1	3	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	09MAR2012 /14	16MAR2012 /-35	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	11MAY2012 /77	24MAY2012 /34	C	1	0	1	5	1
	Investigations/ Aspartate aminotransferase increased/ INCREASED AST	02MAR2012 /7	16MAR2012 /-35	C	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0005/69 /F/A2/N	Skin and subcutaneous tissue disorders/ Palmar-plantar erythrodysesthesia syndrome/ PALMAR-PLANTAR ERYTHRODYSESTHESIA SYNDROME	27APR2012 /63	29JUL2012 /100	C	1	1	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	04MAY2012 /70	10MAY2012 /20	I	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	06APR2012 /42	26JUN2012 /67	I	6	1	1	5	2
306-0006/43 /M/A2/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	10APR2012 /21	14MAY2012 /41	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0006/43 /M/A2/N	General disorders and administration site conditions/ Oedema peripheral/ UPPER LIMB EDEMA	12APR2012 /23	14MAY2012 /41	C	1	1	1	5	1
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	07APR2012 /18	14APR2012 /11	C	1	1	3 /10APR2012 /Unknown	5 [PD]	4
	Blood and lymphatic system disorders/ Coagulopathy/ COAGULOPATHY	08APR2012 /19	14MAY2012 /41	C	1	0	1	5	1
	Hepatobiliary disorders/ Jaundice/ JAUNDICE	07APR2012 /18	14MAY2012 /41	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0006/43 /M/A2/N	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	08APR2012 /19	14MAY2012 /41	C	1	0	1	5	2
306-0007/56 /M/A2/N	General disorders and administration site conditions/ Pain/ GENERAL SORE PAIN	23APR2012 /49	07MAY2012 /21	C	1	1	1	5	3
	General disorders and administration site conditions/ Pyrexia/ FEVER	07MAY2012 /63	07MAY2012 /21	I	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Kyphoscoliosis/ KYPHOSCOLIOSIS	03MAY2012 /59	28NOV2012 /226	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0007/56 /M/A2/N	Musculoskeletal and connective tissue disorders/ Exostosis/ SPINE SPURS FORMATION	03MAY2012 /59	28NOV2012 /226	C	1	0	1	5	1
	Injury, poisoning and procedural complications/ Compression fracture/ COMPRESSION FRACTURE	03MAY2012 /59	28NOV2012 /226	C	1	2	1	5	3
	Nervous system disorders/ Headache/ HEADACHE	10APR2012 /36	04MAY2012 /18	I	1	0	1	5	1
	Nervous system disorders/ Hypoaesthesia/ NUMBNESS SENSATION OVER LEFT FACE	02MAY2012 /58	14JUN2012 /59	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0007/56 /M/A2/N	Nervous system disorders/ Spinal cord compression/ SPINAL CORD COMPRESSION	23APR2012 /49	28NOV2012 /226	C	1	2	1	5	3
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastatic pain/ WORSENING BONE PAIN DUE TO BONE METASTASIS	16MAR2012 /11	28NOV2012 /226	C	1	1	1	5	3
	Nervous system disorders/ Hyperreflexia/ GENERAL HYPERREFLEXIA	16APR2012 /42	04MAY2012 /18	C	1	0	1	5	1
	Gastrointestinal disorders/ Tongue discolouration/ TONGUE WHITISH COATING	23APR2012 /49	20MAY2012 /34	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0007/56 /M/A2/N	Investigations/ Urine output decreased/ DECREASE URINE AMOUNT	14MAY2012 /70	21MAY2012 /35	I	1	0	1	5	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	07MAY2012 /63	04JUN2012 /49	I	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	27APR2012 /53	11MAY2012 /25	I	1	1	1	5	2
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	19MAR2012 /14	25MAR2012 /-22	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0008/40 /M/A2/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	12MAR2012 /0	12MAR2012 /-56	C	1	0	1	4	1
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	19APR2012 /38	23APR2012 /-14	I	1	0	1	5	1
	Investigations/ Aspartate aminotransferase increased/ INCREASED ASPARTATE AMINOTRANSFERASE	30APR2012 /49	12JUN2012 /36	C	1	0	1	5	3
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	15MAR2012 /3	26MAR2012 /-42	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0008/40 /M/A2/Y	Gastrointestinal disorders/ Abdominal distension/ ABDOMEN FULLNESS	19APR2012 /38	06MAY2012 /-1	C	1	1	1	5	2
	Reproductive system and breast disorders/ Benign prostatic hyperplasia/ BENIGN PROSTATIC HYPERPLASIA	19MAR2012 /7	12JUN2012 /36	I	1	3	1	5	2
306-0011/47 /M/A2/Y	Musculoskeletal and connective tissue disorders/ Neck pain/ NECK SORENESS	08MAY2012 /54	08MAY2012 /-22	C	1	1	1	5	1
	Cardiac disorders/ Sinus tachycardia/ SINUS TACHYCARDIA	01JUN2012 /78	02JUN2012 /3	C	1	3	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0011/47 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	22MAR2012 /7	02JUN2012 /3	C	1	1	1	4	2
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Tumour embolism/ PULMONARY TUMOR EMBOLISM	06APR2012 /22	02JUN2012 /3	I	4	1	1	5 [PD]	3
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL CRAMPING PAIN	26MAY2012 /72	02JUN2012 /3	I	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Epistaxis/ NASAL BLEEDING	25MAY2012 /71	25MAY2012 /-5	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0011/47 /M/A2/Y	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	23MAY2012 /69	23MAY2012 /-7	I	1	1	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	12APR2012 /28	09MAY2012 /-21	I	1	1	3 /18APR2012 /26APR2012	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	08APR2012 /24	09APR2012 /-51	C	1	0	1	5	1
	Eye disorders/ Dry eye/ DRY EYES	09MAY2012 /55	09MAY2012 /-21	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0012/61 /M/A2/N	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT ABDOMINAL PAIN	12OCT2012 /193	22NOV2012 /72	I	1	1	1	5	2
	Gastrointestinal disorders/ Oesophageal variceshaemorrhage/ ESOPHAGEAL VARICES BLEEDING	16OCT2012 /197	22NOV2012 /72	I	1	3	1	5 [CD]	3
	Musculoskeletal and connective tissue disorders/ Back pain/ LUMBAR PAIN	07OCT2012 /188	22NOV2012 /72	I	1	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ MILD FEVER	26MAY2012 /54	26MAY2012 /-108	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0012/61 /M/A2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	28SEP2012 /179	28OCT2012 /47	I	1	1	1	5	2
	Gastrointestinal disorders/ Oesophageal varices haemorrhage/ ESOPHAGEAL VARICES BLEEDING	28SEP2012 /179	02OCT2012 /21	I	1	3	1	4 [CD]	3
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	21MAY2012 /49	31MAY2012 /-103	I	1	2	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	02AUG2012 /122	05AUG2012 /-37	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0012/61 /M/A2/N	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	30JUL2012 /119	02AUG2012 /-40	C	2	2	1	5	3
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	21MAY2012 /49	31MAY2012 /-103	C	2	2	1	5	2
	Gastrointestinal disorders/ Oesophageal varices haemorrhage/ ESOPHAGEAL VARICES HEMORRHAGE	29JUL2012 /118	06AUG2012 /-36	I	1	3	3 /30JUL2012 /13AUG2012	5[CD]	3
	Gastrointestinal disorders/ Lower gastrointestinal haemorrhage/ LOWER GASTROINTESTINAL BLEEDING	25JUL2012 /114	29JUL2012 /-44	I	1	1	1	4[CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0012/61 /M/A2/N	Gastrointestinal disorders/ Lower gastrointestinal haemorrhage/ LOWER GASTROINTESTINAL BLEEDING	19MAY2012 /47	31MAY2012 /-103	I	1	1	3 /21MAY2012 /04JUN2012	4 [CD]	3
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	16OCT2012 /197	22NOV2012 /72	C	1	0	1	5	4
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASE	22OCT2012 /203	25OCT2012 /44	C	1	0	1	5	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	28SEP2012 /179	22NOV2012 /72	I	1	2	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0012/61 /M/A2/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL CRAMPING PAIN	29JUL2012 /118	06AUG2012 /-36	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Hiccups/ HICCUP	29JUL2012 /118	29JUL2012 /-44	C	1	0	1	5	1
	Vascular disorders/ Angiodysplasia/ ANGIODYSPLASIA	30MAY2012 /58	22NOV2012 /72	C	1	0	1	5	1
	Vascular disorders/ Hypertension/ HYPERTENSION	30APR2012 /28	07MAY2012 /-127	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0012/61 /M/A2/N	Musculoskeletal and connective tissue disorders/ Exostosis/ LUMBAR SPINE SPUR	25MAY2012 /53	22NOV2012 /72	C	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Intervertebral disc degeneration/ DEGENERATIVE CHANGE OF LUMBAR SPINE	25MAY2012 /53	22NOV2012 /72	C	1	0	1	5	1
	Gastrointestinal disorders/ Portal hypertensive gastropathy/ PORTAL HYPERTENSIVE GASTROPATHY	22MAY2012 /50	22NOV2012 /72	C	1	1	1	5	2
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	16OCT2012 /197	21OCT2012 /40	C	2	0	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0014/47 /M/A2/Y	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	07JUN2012 /49	20JUN2012 /19	I	1	1	1	5	2
	Infections and infestations/ Pneumonia/ PNEUMONIA	18JUN2012 /60	20JUN2012 /19	C	1	1	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	05JUN2012 /47	20JUN2012 /19	I	1	1	1	5	1
	Gastrointestinal disorders/ Epigastric discomfort/ EPIGASTRIC DISCOMFORT	04MAY2012 /15	20JUN2012 /19	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0014/47 /M/A2/Y	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	05JUN2012 /47	20JUN2012 /19	C	1	2	1	5	1
	Hepatobiliary disorders/ Jaundice/ JAUNDICE	05JUN2012 /47	20JUN2012 /19	C	1	0	1	5	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	05JUN2012 /47	20JUN2012 /19	C	1	0	1	5	1
	General disorders and administration site conditions/ Non-cardiac chest pain/ NON-CARDIAC CHEST PAIN	18MAY2012 /29	20JUN2012 /19	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0014/47 /M/A2/Y	General disorders and administration site conditions/ Disease progression/ MALIGNANT DISEASE OF HEPATOCELLULAR CARCINOMA	05JUN2012 /47	20JUN2012 /19	C	4	3	1	5 [PD]	4
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ (RIGHT) PLEURAL EFFUSION	16JUN2012 /58	20JUN2012 /19	C	1	2	1	5	3
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	16JUN2012 /58	20JUN2012 /19	C	1	2	1	5	2
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	11MAY2012 /22	17MAY2012 /-15	C	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0014/47 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Hiccups/ HICCUP	12JUN2012 /54	20JUN2012 /19	I	1	1	1	5	2
	General disorders and administration site conditions/ Non-cardiac chest pain/ NON-CARDIAC CHEST PAIN	11MAY2012 /22	17MAY2012 /-15	I	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ (RIGHT) PLEURAL EFFUSION	06JUN2012 /48	15JUN2012 /14	C	1	2	1	5	2
306-0017/49 /M/A2/Y	General disorders and administration site conditions/ Oedema peripheral/ LOW LEGS EDEMA	19AUG2012 /38	13SEP2012 /21	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0017/49 /M/A2/Y	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	19SEP2012 /69	27SEP2012 /35	C	1	0	1	5	3
	Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE CLAMPING	12JUL2012 /0	14JUL2012 /-40	I	1	0	1	5	1
	Gastrointestinal disorders/ Ascites/ ASCITES	16AUG2012 /35	23AUG2012 /0	C	1	1	1	5	2
	Skin and subcutaneous tissue disorders/ Ecchymosis/ ECHYMOSIS OF ABDOMINAL WALL	24AUG2012 /43	30SEP2012* /38	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0017/49 /M/A2/Y	Gastrointestinal disorders/ Ascites/ MASSIVE ASCITES	23AUG2012 /42	16NOV2012 /85	C	1	3	1	5	3
	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINEMIA	19SEP2012 /69	16NOV2012 /85	C	1	0	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ LOW LEGS EDEMA	13SEP2012 /63	16NOV2012 /85	C	1	1	1	5	3
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Liver carcinoma ruptured/ HEPATOCELLULAR CARCINOMA RUPTURE	23AUG2012 /42	30AUG2012 /7	C	1	2	1	5[CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0017/49 /M/A2/Y	Gastrointestinal disorders/ Eructation/ BELCHING	31JUL2012 /19	23AUG2012 /0	I	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	19AUG2012 /38	16NOV2012 /85	C	1	1	1	5	3
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	19AUG2012 /38	05SEP2012 /13	C	1	0	1	5	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	31JUL2012 /19	19AUG2012 /-4	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0017/49 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ MILD DYSPNEA	19AUG2012 /38	16NOV2012 /85	I	1	2	1	5	1
306-0019/78 /M/A2/N	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	22OCT2012 /61	03DEC2012 /35	C	1	0	1	4	2
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	26NOV2012 /96	03DEC2012 /35	C	1	2	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	23NOV2012 /93	04DEC2012 /36	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0019/78 /M/A2/N	General disorders and administration site conditions/ Oedema peripheral/ LOWER LEG EDEMA	27AUG2012 /5	03SEP2012 /-56	C	1	1	1	4	1
	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRALGIA	06OCT2012 /45	29OCT2012 /0	I	1	1	1	5	2
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING SKIN	24NOV2012 /94	24NOV2012 /26	I	1	1	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	22NOV2012 /92	04DEC2012 /36	C	1	2	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0019/78 /M/A2/N	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	22NOV2012 /92	26NOV2012 /28	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	17SEP2012 /26	04DEC2012 /36	C	1	1	1	5	1
	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	22NOV2012 /92	29NOV2012 /31	C	1	1	1	5	3
	Gastrointestinal disorders/ Vomiting/ VOMITING	22NOV2012 /92	23NOV2012 /25	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0019/78 /M/A2/N	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINEMIA	22NOV2012 /92	29NOV2012 /31	C	1	1	1	5	3
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT FOOT PAIN	24SEP2012 /33	08OCT2012 /-21	C	1	1	1	5	1
	Hepatobiliary disorders/ Hepatic pain/ HEPATIC PAIN	19NOV2012 /89	04DEC2012 /36	C	1	1	1	4 [PD]	3
	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	02SEP2012 /11	12SEP2012 /-47	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0019/78 /M/A2/N	Gastrointestinal disorders/ Ascites/ MILD ASCITES	05NOV2012 /75	04DEC2012 /36	C	1	1	1	4	2
306-0020/63 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	20DEC2012 /77	07JUN2013 /169	I	1	1	1	4	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	22NOV2012 /49	06DEC2012 /-14	C	1	0	1	4	2
	Skin and subcutaneous tissue disorders/ Dry skin/ DRY SKIN	15NOV2012 /42	07JUN2013 /169	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0020/63 /M/A2/N	Gastrointestinal disorders/ Small intestinal haemorrhage/ DUODENAL HEMORRHAGE	25OCT2012 /21	01NOV2012 /-49	C	1	3	1	5 [CD]	3
	Gastrointestinal disorders/ Abdominal pain upper/ HUNGER PAIN	04OCT2012 /0	07JUN2013 /169	I	1	1	1	5	2
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	09OCT2012 /5	16OCT2012 /-65	C	1	1	3 /11OCT2012 /18OCT2012	4	3
	General disorders and administration site conditions/ Pyrexia/ FEVER	09JAN2013 /97	16JAN2013 /27	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0023/68 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNING NOSE	09JAN2013 /43	13JAN2013 /11	I	1	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK SORENESS	18JAN2013 /52	28JUN2013 /177	I	1	0	1	4	1
	Gastrointestinal disorders/ Constipation/ MILD CONSTIPATION	02JAN2013 /36	28JUN2013 /177	I	1	1	1	4	1
	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT PAIN	25DEC2012 /28	28JUN2013 /177	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0023/68 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Cough/ MILD COUGH	07DEC2012 /10	25DEC2012 /-8	I	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Hiccups/ HICCUP	12JAN2013 /46	13JAN2013 /11	C	1	1	1	4	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	10JAN2013 /44	28JUN2013 /177	I	1	1	1	4	1
	Gastrointestinal disorders/ Abdominal distension/ EPIGASTRIC FULLNESS	07DEC2012 /10	25DEC2012 /-8	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0023/68 /M/A2/Y	Investigations/ Weight decreased/ BODY WEIGHT LOSS	02JAN2013 /36	28JUN2013 /177	C	1	0	1	5	1
306-0026/58 /M/A2/N	Gastrointestinal disorders/ Ascites/ ASCITES	25APR2013 /80	18JUL2013 /-82	C	1	0	1	4	1
	Ear and labyrinth disorders/ Vertigo/ VERTIGO	07NOV2013 /276	09JUN2015 /609	C	1	1	1	4	1
	Infections and infestations/ Nasopharyngitis/ COMMON COLD	17MAY2013 /102	20MAY2013 /-141	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0026/58 /M/A2/N	Psychiatric disorders/ Insomnia/ INSOMNIA	19OCT2013 /257	25OCT2013 /17	I	1	1	1	4	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	19OCT2013 /257	23OCT2013 /15	I	1	1	1	4	2
	Nervous system disorders/ Headache/ HEADACHE	21FEB2013 /17	09MAY2013 /-152	I	1	0	1	4	1
	Gastrointestinal disorders/ Enteritis/ INFECTIVE ENTERITIS	19OCT2013 /257	04NOV2013 /27	I	1	1	1	4[Infective Enteritis]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0026/58 /M/A2/N	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	03OCT2013 /241	09JUN2015 /609	C	1	0	1	4	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	26SEP2013 /234	03OCT2013 /-5	I	1	1	1	4	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	25FEB2013 /21	03JUN2013 /-127	I	1	1	1	4	1
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	04JUL2013 /150	11JUL2013 /-89	C	1	0	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0026/58 /M/A2/N	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	04JUL2013 /150	11JUL2013 /-89	C	1	0	1	4	3
	Ear and labyrinth disorders/ Vertigo/ VERTIGO	25FEB2013 /21	13JUN2013 /-117	C	1	0	1	4	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	17MAY2013 /102	18MAY2013 /-143	C	1	1	1	4	1
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	21FEB2013 /17	09JUN2015 /609	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0026/58 /M/A2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	16MAY2013 /101	09JUN2015 /609	C	1	0	1	4	1
306-0027/67 /M/A2/N	Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT HIP PAIN	26FEB2014 /372	26MAR2014 /-98	I	1	1	1	4	2
	General disorders and administration site conditions/ Non-cardiac chest pain/ NON-CARDIAC CHEST PAIN	17APR2013 /57	26JUN2013 /-371	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	04DEC2013 /288	Unknown/NA	I	6	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0027/67 /M/A2/N	Eye disorders/ Dry eye/ DRY EYE	30APR2014 /435	Unknown/NA	C	6	1	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Nasal obstruction/ NASAL OBSTRUCTION	13NOV2013 /267	20NOV2013 /-224	I	1	0	1	4	1
	General disorders and administration site conditions/ Nodule/ LEFT EYE NODULE	09APR2014 /414	18APR2014 /-75	C	1	1	1	4	1
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	26MAR2014 /400	09APR2014 /-84	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0027/67 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	13NOV2013 /267	04DEC2013 /-210	I	1	0	1	4	1
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	26MAR2014 /400	09APR2014 /-84	C	1	0	1	4	1
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	12MAR2014 /386	26MAR2014 /-98	C	1	0	3 /19MAR2014 /02APR2014	4	3
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	12MAR2014 /386	26MAR2014 /-98	C	1	0	3 /19MAR2013 /02APR2014	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0027/67 /M/A2/N	General disorders and administration site conditions/ Oedema/ LOCALIZED EDEMA (FACE AND FEET)	29MAY2013 /99	05JUN2013 /-392	C	1	0	1	4	1
	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	05MAR2014 /379	06AUG2014 /35	I	1	1	1	4	1
306-0030/63 /M/A2/N	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT NEOPLASM PROGRESSION	29JUN2013 /67	18JUL2013 /44	C	4	0	1	4 [PD]	5
	Vascular disorders/ Hypertension/ HYPERTENSION	17JUN2013 /55	18JUL2013 /44	C	1	1	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0030/63 /M/A2/N	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	02MAY2013 /9	18JUL2013 /44	C	1	1	1	4	2
	Gastrointestinal disorders/ Mouth ulceration/ ORAL ULCER	08JUN2013 /46	08JUN2013 /4	C	1	1	1	5	2
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	03MAY2013 /10	03MAY2013 /-32	I	1	1	1	4	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	02MAY2013 /9	18JUL2013 /44	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0030/63 /M/A2/N	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	24JUN2013 /62	18JUL2013 /44	C	1	1	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Lung consolidation/ RIGHT LOWER LUNG CONSOLIDATION	19JUN2013 /57	18JUL2013 /44	C	1	1	1	4	2
	Respiratory, thoracic and mediastinal disorders/ Pneumonitis/ PNEUMONITIS	01MAY2013 /8	08MAY2013 /-27	I	1	1	1	4 [CD]	2
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	21JUN2013 /59	18JUL2013 /44	C	1	1	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0030/63 /M/A2/N	Eye disorders/ Conjunctival haemorrhage/ SUBCONJUNCTIVAL HEMORRHAGE	18JUN2013 /56	18JUL2013 /44	C	1	1	1	4	2
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	17JUN2013 /55	21JUN2013 /17	C	1	1	1	4	4
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	07JUN2013 /45	16JUN2013 /12	C	1	1	1	4	3
	Musculoskeletal and connective tissue disorders/ Bone pain/ BONE PAIN	30APR2013 /7	18JUL2013 /44	I	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0030/63 /M/A2/N	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRALGIA	03MAY2013 /10	18JUL2013 /44	C	1	0	1	5	2
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	04JUN2013 /42	18JUL2013 /44	C	1	3	1	4 [PD]	3
	General disorders and administration site conditions/ Pyrexia/ FEVER	30APR2013 /7	30APR2013 /-35	I	1	1	3 /30APR2013 /08MAY2013	4	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA (LEFT ANKLE JOINT PAIN)	28MAY2013 /35	18JUL2013 /44	C	1	3	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0030/63 /M/A2/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	21MAY2013 /28	18JUL2013 /44	C	1	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Myositis/ MYOSITIS (LEFT LOW EXTREMITY MUSCLE SORENESS)	14MAY2013 /21	04JUN2013 /0	C	1	1	1	4	1
	Vascular disorders/ Hypertension/ BLOOD PRESSURE HIGH	07JUN2013 /45	07JUN2013 /3	C	1	1	1	4	2
306-0031/40 /M/A2/N	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT PAIN	11JUN2013 /27	17MAY2014 /304	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0031/40 /M/A2/N	Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	05JUN2013 /21	26JUN2013 /-21	I	1	0	1	3	1
	Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA(SKIN ITCHING)	22MAY2013 /7	24JUL2013 /7	I	1	1	1	3	2
306-0034/65 /M/A2/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	25JUL2013 /24	09AUG2013 /15	I	1	1	1	4	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA(POOR APPETITE)	01JUL2013 /0	09AUG2013 /15	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0034/65 /M/A2/Y	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	05AUG2013 /35	08AUG2013 /14	C	1	2	1	4	3
	Gastrointestinal disorders/ Haemorrhoidal haemorrhage/ HEMORRHOID HEMORRHAGE	18JUL2013 /17	22JUL2013 /-3	C	1	1	1	4	2
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	04AUG2013 /34	09AUG2013 /15	C	1	3	1	4	1
	Nervous system disorders/ Altered state of consciousness/ CONSCIOUSNESS DISTURBANCE	31JUL2013 /30	03AUG2013 /9	C	1	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0034/65 /M/A2/Y	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	05AUG2013 /35	09AUG2013 /15	I	1	1	1	4	1
	Gastrointestinal disorders/ Oesophageal variceshaemorrhage/ ESOPHAGEAL VARICES HEMORRHAGE	03AUG2013 /33	09AUG2013 /15	C	1	3	1	4	3
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS(BILATERAL FOOT)	18JUL2013 /17	09AUG2013 /15	C	1	1	1	4	1
	Skin and subcutaneous tissue disorders/ Skin ulcer/ SKIN ULCERATION(COCCYGEAL AREA)	25JUL2013 /24	09AUG2013 /15	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0034/65 /M/A2/Y	Nervous system disorders/ Paraesthesia/ PARESTHESIA(RIGHT HIP)	08JUL2013 /7	09AUG2013 /15	C	1	1	1	4	2
	Renal and urinary disorders/ Urinary retention/ URINARY RETENTION	08JUL2013 /7	09AUG2013 /15	C	1	2	1	4	2
	Musculoskeletal and connective tissue disorders/ Bone pain/ BONE PAIN	11JUL2013 /10	09AUG2013 /15	C	1	1	1	4	2
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT NEOPLASM PROGRESSION	09AUG2013 /39	09AUG2013 /15	C	4	0	1	4 [PD]	5

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0034/65 /M/A2/Y	Infections and infestations/ Urosepsis/ UROSEPSIS	31JUL2013 /30	09AUG2013 /15	C	1	1	1	4 [PD]	4
	Metabolism and nutrition disorders/ Cachexia/ CACHEXIA	31JUL2013 /30	09AUG2013 /15	C	1	1	1	4	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	31JUL2013 /30	05AUG2013 /11	C	1	2	1	4	2
306-0035/48 /M/A2/Y	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	16SEP2013 /70	11OCT2013 /53	C	1	1	1	4 [PD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0035/48 /M/A2/Y	Gastrointestinal disorders/ Gastrointestinal pain/ GASTROINTESTINAL PAIN	15JUL2013 /7	16SEP2013 /28	I	1	1	1	4	1
	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT PAIN	12AUG2013 /35	16SEP2013 /28	C	1	1	1	4	1
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	29JUL2013 /21	12AUG2013 /-7	I	1	0	1	3	1
	Gastrointestinal disorders/ Gastrooesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISEASE	22JUL2013 /14	01DEC2013 /104	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0035/48 /M/A2/Y	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	23SEP2013 /77	01DEC2013 /104	C	1	0	1	4	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	16SEP2013 /70	01DEC2013 /104	I	1	1	1	4	2
	Gastrointestinal disorders/ Ascites/ ASCITES	22AUG2013 /45	01DEC2013 /104	C	1	2	1	4	3
	General disorders and administration site conditions/ Malaise/ MALAISE	22JUL2013 /14	01DEC2013 /104	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0035/48 /M/A2/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	18SEP2013 /72	01OCT2013 /43	I	1	0	1	4	1
306-0036/73 /M/A2/Y	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	13AUG2013 /35	27AUG2013 /7	C	1	1	1	3	3
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	03SEP2013 /56	25NOV2013 /97	C	1	1	2	3	3
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	27AUG2013 /49	07SEP2013 /18	C	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0036/73 /M/A2/Y	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	10SEP2013 /63	25NOV2013 /97	C	1	0	1	4	1
	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	13AUG2013 /35	03SEP2013 /14	C	1	0	1	4	1
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	10SEP2013 /63	25NOV2013 /97	C	1	1	1	3	2
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	27AUG2013 /49	10SEP2013 /21	C	1	1	2	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0036/73 /M/A2/Y	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	27AUG2013 /49	03SEP2013 /14	C	1	1	1	3	4
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	10SEP2013 /63	25NOV2013 /97	C	1	0	1	4	2
	Gastrointestinal disorders/ Abdominal distension/ EPIGASTRIC FULLNESS	27AUG2013 /49	25NOV2013 /97	C	1	1	1	4	1
	Skin and subcutaneous tissue disorders/ Alopecia/ ALOPECIA	20AUG2013 /42	24SEP2013 /35	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0036/73 /M/A2/Y	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ SHOULDER PAIN	20AUG2013 /42	20AUG2013 /0	C	1	0	1	4	1
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	14SEP2013 /67	25NOV2013 /97	C	1	1	1	4	2
	Infections and infestations/ Diarrhoea infectious/ INFECTIOUS DIARRHEA	07SEP2013 /60	14SEP2013 /25	C	1	1	1	4 [PD]	2
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	13AUG2013 /35	27AUG2013 /7	C	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0036/73 /M/A2/Y	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	07SEP2013 /60	10SEP2013 /21	C	1	0	1	4	3
306-0038/66 /M/A2/N	Nervous system disorders/ Paraesthesia/ PARESTHESIA(FINGERS AND TOES)	21AUG2013 /0	30OCT2013 /0	C	1	1	1	5	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	25SEP2013 /35	04MAY2014 /186	I	1	0	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ COUGH WITH SOME BLOOD TINGED SPUTUM	20NOV2013 /91	04MAY2014 /186	I	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0038/66 /M/A2/N	Gastrointestinal disorders/ Abdominal pain lower/ RIGHT LOWER QUADRANT PAIN	25SEP2013 /35	04MAY2014 /186	I	1	0	1	4	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	11SEP2013 /21	17SEP2013 /-43	I	1	0	1	5	1
	Renal and urinary disorders/ Urinary retention/ URINARY RETENTION	11SEP2013 /21	17SEP2013 /-43	I	1	0	1	5	1
	Nervous system disorders/ Paraesthesia/ PARESTHSIA	30OCT2013 /70	04MAY2014 /186	C	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0038/66 /M/A2/N	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH (RIGHT ARM)	04SEP2013 /14	11SEP2013 /-49	C	1	0	1	2	1
	General disorders and administration site conditions/ Non-cardiac chest pain/ NON-CARDIAN CHEST PAIN	23OCT2013 /63	30OCT2013 /0	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	16OCT2013 /56	04MAY2014 /186	I	1	1	1	4	2
	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	28AUG2013 /7	04MAY2014 /186	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0038/66 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	28AUG2013 /7	16OCT2013 /-14	I	1	1	1	4	1
	Skin and subcutaneous tissue disorders/ Dry skin/ DRY SKIN	16OCT2013 /56	04MAY2014 /186	I	1	0	1	4	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA(BILATERAL SHOULDERS AND LOWER LIMBS)	03OCT2013 /43	04MAY2014 /186	I	1	1	1	3	1
306-0039/62 /M/A2/Y	General disorders and administration site conditions/ Fatigue/ FATIGUE	08OCT2013 /49	15DEC2013 /47	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0039/62 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ HEMOPTYSIS	27AUG2013 /7	09SEP2013 /-50	I	1	1	1	4	2
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	19NOV2013 /91	09DEC2013 /41	C	1	3	1	4 [PD]	4
	Respiratory, thoracic and mediastinal disorders/ Bronchial obstruction/ BRONCHIAL OBSTRUCTION	15OCT2013 /56	15DEC2013 /47	C	1	1	1	4	2
	General disorders and administration site conditions/ Oedema peripheral/ LIMBS EDEMA	23NOV2013 /95	15DEC2013 /47	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0039/62 /M/A2/Y	Gastrointestinal disorders/ Haematochezia/ BLOODY-COATED STOOL	27NOV2013 /99	15DEC2013 /47	I	1	1	1	4	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	27AUG2013 /7	15DEC2013 /47	C	1	1	1	4	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	20NOV2013 /92	15DEC2013 /47	I	1	1	1	4	2
	Psychiatric disorders/ Anxiety/ ANXIETY	20NOV2013 /92	23NOV2013 /25	I	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0040/44 /F/A2/Y	Cardiac disorders/ Sinus tachycardia/ SINUS TACHYCARDIA (NON-CARDIAC)	01APR2014 /189	08APR2014 /35	C	1	0	1	5	1
	Nervous system disorders/ Dizziness/ DIZZINESS	01APR2014 /189	08APR2014 /35	I	1	0	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	18MAR2014 /175	20JUN2014 /108	I	1	1	1	5	2
	Vascular disorders/ Hot flush/ HOT FLASHES	24SEP2013 /0	24SEP2013 /-161	C	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0040/44 /F/A2/Y	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	04MAR2014 /161	09JUL2014 /127	C	1	0	1	4	3
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	18FEB2014 /147	04MAR2014 /0	C	1	0	1	4	2
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	07FEB2014 /136	18FEB2014 /-14	C	1	0	1	4	2
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	07FEB2014 /136	18FEB2014 /-14	C	2	0	3 /11FEB2014 /25FEB2014	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0040/44 /F/A2/Y	Gastrointestinal disorders/ Abdominal pain lower/ LOWER ABDOMINAL PAIN	07FEB2014 /136	09JUL2014 /127	I	1	0	1	4	1
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	21JAN2014 /119	07FEB2014 /-25	C	1	0	1	4	2
	Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT HIP PAIN	21JAN2014 /119	25MAR2014 /21	I	1	1	1	4	2
	Eye disorders/ Vision blurred/ BLURRED VISION(LEFT EYE)	21OCT2013 /27	09JUL2014 /127	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0040/44 /F/A2/Y	General disorders and administration site conditions/ Injection site reaction/ INJECTION SITE REACTION	24DEC2013 /91	24DEC2013 /-70	C	1	0	1	2	1
	Musculoskeletal and connective tissue disorders/ Back pain/ LOWER BACK PAIN	03DEC2013 /70	09JUL2014 /127	I	1	1	1	4	1
	Gastrointestinal disorders/ Abdominal distension/ BLOATING	03DEC2013 /70	09JUL2014 /127	I	1	1	1	4	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	21OCT2013 /27	29OCT2013 /-126	C	1	2	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0040/44 /F/A2/Y	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	08OCT2013 /14	26APR2014 /53	I	1	1	1	4	2
	Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RUNNING NOSE	10OCT2013 /16	14OCT2013 /-141	I	1	1	1	4	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	10OCT2013 /16	07JAN2014 /-56	I	1	1	1	4	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	03DEC2013 /70	09DEC2013 /-85	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0040/44 /F/A2/Y	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	08APR2014 /196	20JUN2014 /108	I	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT LEG SORENESS	18MAR2014 /175	25MAR2014 /21	I	1	1	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	08APR2014 /196	17APR2014 /44	I	1	0	1	5	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	18MAR2014 /175	09JUL2014 /127	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0040/44 /F/A2/Y	Gastrointestinal disorders/ Abdominal pain lower/ LOWER ABDOMINAL PAIN	29OCT2013 /35	19NOV2013 /-105	I	1	0	1	4	1
	Infections and infestations/ Oral herpes/ HERPES SIMPLEX AT RIGHT UPPER LIP	25OCT2013 /31	29OCT2013 /-126	C	1	0	1	4	1
	Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	07FEB2014 /136	12FEB2014 /-20	C	1	1	1	4	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	31DEC2013 /98	07JAN2014 /-56	C	1	2	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0040/44 /F/A2/Y	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	19NOV2013 /56	26NOV2013 /-98	C	1	2	1	4	3
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	08APR2014 /196	28APR2014 /55	C	1	1	1	5	3
	Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT HIP PAIN	25MAR2014 /182	09JUL2014 /127	I	1	1	1	4	3
306-0041/62 /M/A2/N	Infections and infestations/ Herpes zoster/ HERPES ZOSTER	06JAN2014 /69	28JAN2014 /-14	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0041/62 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	21FEB2014 /115	22FEB2014 /11	I	1	1	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	01MAR2014 /123	01MAR2014 /18	C	1	1	1	5	1
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	10MAR2014 /132	12MAR2014 /29	C	1	2	1	5	4
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	03MAR2014 /125	10MAR2014 /27	C	1	2	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0041/62 /M/A2/N	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	01MAR2014 /123	03MAR2014 /20	C	1	2	1	5	4
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	24FEB2014 /118	12MAR2014 /29	I	1	1	1	4	1
	Skin and subcutaneous tissue disorders/ Skin ulcer/ SKIN ULCERATION	12MAR2014 /134	12MAR2014 /29	C	1	3	1	5	2
	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	10MAR2014 /132	12MAR2014 /29	C	1	1	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0041/62 /M/A2/N	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	03MAR2014 /125	12MAR2014 /29	C	1	1	1	4	2
	Vascular disorders/ Superior vena cava syndrome/ SUPERIOR VENA CAVA SYNDROME	30JAN2014 /93	12MAR2014 /29	C	1	1	1	4 [PD]	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA (WORSENING)	10MAR2014 /132	12MAR2014 /29	C	1	1	1	5	3
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	02MAR2014 /124	10MAR2014 /27	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0041/62 /M/A2/N	Metabolism and nutrition disorders/ Hyperammonaemia/ HYPERAMMONEMIA	05MAR2014 /127	12MAR2014 /29	C	1	1	1	4	2
	General disorders and administration site conditions/ Oedema peripheral/ LEFT UPPER EXTREMITY EDEMA	30JAN2014 /93	12MAR2014 /29	C	1	1	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ HEMOPTYSIS	28FEB2014 /122	12MAR2014 /29	I	1	1	1	4	2
	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	01MAR2014 /123	03MAR2014 /20	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0041/62 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	01MAR2014 /123	10MAR2014 /27	I	1	1	1	4	2
	Blood and lymphatic system disorders/ Lymph node pain/ LYMPH NODE PAIN(LEFT SUBAXILLARY)	28JAN2014 /91	12MAR2014 /29	I	1	0	1	4	1
	Infections and infestations/ Candida infection/ MONILIAL INFECTION OF ORAL CAVITY	28FEB2014 /122	12MAR2014 /29	C	1	1	1	5	2
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT NEOPLASM PROGRESSION	02MAR2014 /124	12MAR2014 /29	C	4	1	1	4 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0043/56 /M/A2/N	Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	31MAY2014 /12	09JUN2014 /-56	I	1	0	1	2	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	16JUN2014 /28	06AUG2014 /2	I	1	1	1	2	1
	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	04SEP2014 /108	07OCT2014 /64	C	1	0	1	5	3
	General disorders and administration site conditions/ Injection site reaction/ INJECTION SITE REACTION	05JUN2014 /17	01JUL2014 /-34	I	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0043/56 /M/A2/N	Metabolism and nutrition disorders/ Cachexia/ CACHEXIA	19AUG2014 /92	07OCT2014 /64	C	1	1	1	5	1
	Hepatobiliary disorders/ Hepatomegaly/ HEPATOMEGALY	19AUG2014 /92	07OCT2014 /64	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	09JUN2014 /21	07OCT2014 /64	C	1	0	1	4	2
	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	10JUL2014 /52	21JUL2014 /-14	C	1	0	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0043/56 /M/A2/N	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH(FOREHEAD)	04SEP2014 /108	02OCT2014 /59	I	1	0	1	4	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	05AUG2014 /78	07OCT2014 /64	C	1	1	1	4	2
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH(BOTH FOREARM)	29MAY2014 /10	11JUN2014 /-54	I	1	1	1	2	2
	Investigations/ Weight decreased/ WEIGHT LOSS	10JUL2014 /52	07OCT2014 /64	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0043/56 /M/A2/N	General disorders and administration site conditions/ Injection site reaction/ INJECTION SITE REACTION	01JUL2014 /43	06AUG2014 /2	I	1	0	1	2	2
307-0002/61 /M/A2/N	Gastrointestinal disorders/ Vomiting/ VOMITING	16FEB2012 /105	08APR2012 /80	C	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Muscular weakness/ LEG WEAKNESS	15DEC2011 /42	05JAN2012 /-14	C	1	0	1	5	2
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	05JAN2012 /63	21FEB2012 /33	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0002/61 /M/A2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	05JAN2012 /63	16APR2012 /88	I	1	1	1	5	1
	Nervous system disorders/ Headache/ HEADACHE	05JAN2012 /63	19JAN2012 /0	C	1	1	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus generalised/ PRURITUS (GENERAL)	17NOV2011 /14	16FEB2012 /28	I	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	20NOV2011 /17	01DEC2011 /-49	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0002/61 /M/A2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	24NOV2011 /21	01DEC2011 /-49	I	1	0	1	5	1
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	08DEC2011 /35	22DEC2011 /-28	C	1	0	1	3	1
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	08DEC2011 /35	22DEC2011 /-28	C	1	1	1	3	1
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	10NOV2011 /7	25NOV2011 /-55	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0002/61 /M/A2/N	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	12DEC2011 /39	19JAN2012 /0	I	1	1	1	3	2
	General disorders and administration site conditions/ Injection site reaction/ INJECTION SITE REACTION	04NOV2011 /1	01DEC2011 /-49	I	1	0	1	2	1
307-0003/68 /M/A2/N	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	07AUG2012 /271	26NOV2012 /132	C	1	2	1	5	2
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	02AUG2012 /266	07AUG2012 /21	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0003/68 /M/A2/N	Musculoskeletal and connective tissue disorders/ Muscle spasms/ LEG MUSCLE SPASM	08MAY2012 /180	29MAY2012 /-49	I	1	1	1	5	2
	Gastrointestinal disorders/ Ascites/ WORSENING OF ASCITES	03JAN2012 /54	09FEB2013 /207	C	1	3	1	5	3
	General disorders and administration site conditions/ Malaise/ GENERAL MALAISE	24JUL2012 /257	28AUG2012 /42	I	1	0	1	5	1
	Nervous system disorders/ Lethargy/ LETHARGY	14JUN2012 /217	26JUN2012 /-21	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0003/68 /M/A2/N	Renal and urinary disorders/ Renal impairment/ RENAL FUNCTION IMPAIRMENT	27JAN2012 /78	09FEB2013 /207	I	1	1	3 /24JUL2012 /Unknown	4	2
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	16APR2012 /158	29MAY2012 /-49	C	1	1	1	2	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	15MAY2012 /187	26JUN2012 /-21	I	1	1	1	5	2
	Hepatobiliary disorders/ Cholelithiasis/ CHOLELITHIASIS	31JAN2012 /82	09FEB2013 /207	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0003/68 /M/A2/N	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	31JUL2012 /264	02AUG2012 /16	C	2	1	1	4 [PD]	3
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	20MAR2012 /131	03APR2012 /-105	C	2	1	1	5	2
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	06MAR2012 /117	20MAR2012 /-119	C	1	1	1	2	1
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	27JAN2012 /78	07FEB2012 /-161	C	1	1	1	2	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0003/68 /M/A2/N	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	10JAN2012 /61	07FEB2012 /-161	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	27DEC2011 /47	10JAN2012 /-189	C	2	0	1	5	1
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	27DEC2011 /47	10JAN2012 /-189	C	1	0	1	3	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	27DEC2011 /47	07FEB2012 /-161	C	1	2	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0003/68 /M/A2/N	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LEGS EDEMA	27DEC2011 /47	09FEB2013 /207	C	1	1	1	5	2
307-0004/60 /M/A2/N	Psychiatric disorders/ Agitation/ AGITATION	22JAN2012 /73	18MAR2012 /61	C	1	1	1	5	2
	Psychiatric disorders/ Insomnia/ INSOMNIA	14FEB2012 /96	18MAR2012 /61	C	1	1	1	5	1
	Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	02FEB2012 /84	11FEB2012 /25	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0004/60 /M/A2/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	20JAN2012 /71	18MAR2012 /61	I	1	1	1	5	1
	Metabolism and nutrition disorders/ Hypocalcaemia/ HYPOCALCEMIA	21JAN2012 /72	23JAN2012 /6	C	1	1	1	5	1
	Vascular disorders/ Hypertension/ HYPERTENSION	20JAN2012 /71	21JAN2012 /4	C	1	1	1	5	2
	Injury, poisoning and procedural complications/ Spinal compression fracture/ SPINE CORD COMPRESSION FRACTURE	19JAN2012 /70	18MAR2012 /61	C	1	3	1	5 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0004/60 /M/A2/N	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ CHEST WALL TENDERNESS	03JAN2012 /54	18MAR2012 /61	C	1	1	1	5	1
307-0008/58 /M/A2/Y	Infections and infestations/ Oral candidiasis/ ORAL CANDIDAS	16MAR2012 /87	24MAR2012 /32	C	1	1	1	5	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	15MAR2012 /86	27MAR2012 /35	C	1	2	1	5	1
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	15MAR2012 /86	26MAR2012 /34	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0008/58 /M/A2/Y	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	13MAR2012 /84	15MAR2012 /23	C	2	2	1	5	3
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	13MAR2012 /84	01OCT2012 /223	C	1	0	1	5	3
	Gastrointestinal disorders/ Gastric ulcer/ GASTRIC ULCER	09MAR2012 /80	06AUG2012 /167	C	1	1	1	5	3
	Blood and lymphatic system disorders/ Coagulopathy/ COAGULOPATHY	08MAR2012 /79	22MAR2012 /30	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0008/58 /M/A2/Y	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	08MAR2012 /79	13MAR2012 /21	C	1	2	1	5	1
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	08MAR2012 /79	15MAR2012 /23	C	1	1	1	5	3
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	08MAR2012 /79	13MAR2012 /21	C	2	0	1	5	4
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	01MAR2012* /72	10MAR2012 /18	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0008/58 /M/A2/Y	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	01MAR2012* /72	12MAR2012 /20	C	1	0	1	5	1
	General disorders and administration site conditions/ Malaise/ GENERAL MALAISE	01MAR2012 /72	27MAR2012 /35	I	1	0	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	11MAR2012 /82	19MAR2012 /27	I	1	1	1	5	2
	Gastrointestinal disorders/ Gastrointestinal haemorrhage/ GASTROINTESTINAL BLEEDING	09MAR2012 /80	17MAR2012 /25	I	1	3	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0008/58 /M/A2/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	08MAR2012 /79	01APR2012 /40	I	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRALGIA	14FEB2012 /56	12MAR2012 /20	C	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ HEMOPTYSIS	17JAN2012 /28	27JAN2012 /-25	I	1	1	1	5	1
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	08MAR2012 /79	24APR2012 /63	C	1	0	1	5 [PD]	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0008/58 /M/A2/Y	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	01MAR2012 /72	07MAR2012 /15	C	1	1	1	5	2
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	21FEB2012 /63	08MAR2012 /16	C	1	1	3 /01MAR2012 /Unknown	5	3
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	01MAR2012 /72	15MAR2012 /23	C	2	1	1	5	3
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	21FEB2012 /63	29FEB2012 /8	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0008/58 /M/A2/Y	Gastrointestinal disorders/ Haemorrhoids/ HEMORRHOID	31JAN2012 /42	17MAR2012 /25	I	1	1	1	5	2
	General disorders and administration site conditions/ Injection site reaction/ INJECTION SITE REACTION	27JAN2012 /38	01MAR2012 /9	I	1	0	1	2	1
307-0011/75 /M/A2/N	General disorders and administration site conditions/ Oedema peripheral/ WORSENING OF BILATERAL LEGS EDEMA	13MAR2012 /35	02APR2012 /17	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Lactic acidosis/ LACTIC ACIDOSIS	29MAR2012 /51	02APR2012 /17	C	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0011/75 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	30MAR2012 /52	02APR2012 /17	I	1	3	1	5	3
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	01APR2012 /54	02APR2012 /17	C	1	0	1	5	2
	Metabolism and nutrition disorders/ Hypernatraemia/ HYPERNATREMIA	01APR2012 /54	02APR2012 /17	C	1	0	1	5	4
	Gastrointestinal disorders/ Gastrointestinal haemorrhage/ GASTROINTESTINAL BLEEDING	30MAR2012 /52	02APR2012 /17	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0011/75 /M/A2/N	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	01APR2012 /54	02APR2012 /17	C	1	0	1	5	3
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	28MAR2012 /50	01APR2012 /16	C	1	0	1	5	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	01APR2012 /54	02APR2012 /17	C	1	0	1	5	2
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	28MAR2012 /50	02APR2012 /17	C	1	0	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0011/75 /M/A2/N	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	28MAR2012 /50	01APR2012 /16	C	2	0	1	5	3
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	25MAR2012 /47	28MAR2012 /12	C	1	0	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	28MAR2012 /50	02APR2012 /17	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	01APR2012 /54	01APR2012 /16	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0011/75 /M/A2/N	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	02APR2012 /55	02APR2012 /17	C	1	1	1	5	3
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	29FEB2012 /22	13MAR2012 /-3	C	1	0	1	4	1
	Skin and subcutaneous tissue disorders/ Rash pruritic/ PRURITIC SKIN RASH (GENERAL)	25MAR2012 /47	02APR2012 /17	C	1	1	1	2	3
	Skin and subcutaneous tissue disorders/ Rash pruritic/ PRURITIC SKIN RASH (GENERAL)	24MAR2012 /46	25MAR2012 /9	C	1	1	1	2	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0011/75 /M/A2/N	General disorders and administration site conditions/ Oedema peripheral/ WORSENING OF BILATERAL LEG EDEMA	09MAR2012 /31	13MAR2012 /-3	C	2	1	1	5	3
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	21MAR2012 /43	22MAR2012 /6	C	1	0	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ WORSENING OF BILATERAL LEGS EDEMA	06MAR2012 /28	09MAR2012 /-7	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hyperuricaemia/ WORSENING HYPERURICEMIA	21FEB2012 /14	28FEB2012 /-17	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0011/75 /M/A2/N	Infections and infestations/ Sepsis/ SEPSIS	29MAR2012 /51	02APR2012 /17	C	4	1	1	5[Mucositis , Allergic Skin Reaction]	4
	Skin and subcutaneous tissue disorders/ Dermatitis allergic/ ALLERGIC SKIN REACTION	25MAR2012 /47	02APR2012 /17	C	1	1	1	2	3
	Gastrointestinal disorders/ Stomatitis/ MUCOSITIS ORAL	19MAR2012 /41	02APR2012 /17	C	1	1	1	3	3
	Immune system disorders/ Hypersensitivity/ ALLERGIC REACTION (GENERAL)	24MAR2012 /46	24MAR2012 /8	C	2	1	1	1	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0011/75 /M/A2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	16MAR2012 /38	02APR2012 /17	I	1	1	1	5[Allergic Reaction]	1
	Investigations/ Blood creatinine increased/ CREATININE INCREASED	29FEB2012 /22	01MAR2012 /-15	C	1	1	1	3	2
	Metabolism and nutrition disorders/ Hyperuricaemia/ WORSENING HYPERURICEMIA	13MAR2012 /35	02APR2012 /17	C	1	1	1	3	1
	Metabolism and nutrition disorders/ Hyperuricaemia/ WORSENING HYPERURICEMIA	29FEB2012 /22	13MAR2012 /-3	C	2	1	1	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0011/75 /M/A2/N	Skin and subcutaneous tissue disorders/ Rash pruritic/ PRURITIC SKIN RASH (GENERAL)	13MAR2012 /35	16MAR2012 /0	C	1	1	1	3	1
	Immune system disorders/ Hypersensitivity/ ALLERGIC REACTION (GENERAL)	16MAR2012 /38	24MAR2012 /8	C	2	1	2	2	3
	Skin and subcutaneous tissue disorders/ Rash pruritic/ PRURITIC SKIN RASH (GENERAL)	06MAR2012 /28	13MAR2012 /-3	C	2	1	3 /06MAR2012 /16MAR2012	3	3
	Skin and subcutaneous tissue disorders/ Rash pruritic/ PRURITIC SKIN RASH (GENERAL)	23FEB2012 /16	05MAR2012 /-11	C	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0014/61 /M/A2/Y	Psychiatric disorders/ Insomnia/ INSOMNIA	08AUG2012 /174	08AUG2012 /13	C	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	08AUG2012 /174	08AUG2012 /13	C	1	2	1	5	1
	Injury, poisoning and procedural complications/ Procedural pain/ BIOPSY WOUND PAIN	08AUG2012 /174	11AUG2012 /16	C	1	1	1	5	1
	Nervous system disorders/ Dizziness/ DIZZINESS	07AUG2012 /173	07AUG2012 /12	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0014/61 /M/A2/Y	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING SKIN (NECK)	07AUG2012 /173	07AUG2012 /12	I	1	0	1	5	1
	Vascular disorders/ Hypotension/ HYPOTENSION	06AUG2012 /172	08AUG2012 /13	I	1	1	1	5	2
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	06AUG2012 /172	16AUG2012 /21	C	1	2	1	5	1
	Cardiac disorders/ Bradycardia/ BRADYCARDIA	07AUG2012 /173	07AUG2012 /12	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0014/61 /M/A2/Y	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH (GENERAL)	30MAR2012 /43	30MAR2012 /-118	C	1	0	1	2	2
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	08MAR2012 /21	22MAR2012 /-126	C	1	1	1	5	2
	Nervous system disorders/ Headache/ HEADACHE	12MAR2012 /25	12APR2012 /-105	I	1	1	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	05MAR2012 /18	04APR2012 /-113	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0018/70 /M/A2/N	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	05JUN2013 /356	10JUN2013 /32	C	1	0	1	5	3
	Gastrointestinal disorders/ Ascites/ ASCITES	05JUN2013 /356	18JUN2013 /40	C	1	1	1	5	2
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	04JUN2013 /355	10JUN2013 /32	C	1	1	1	5	2
	General disorders and administration site conditions/ Injection site rash/ SKIN RASH (INJECTION SITE: BUTTOCK)	08NOV2012 /147	02APR2013 /-37	I	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0018/70 /M/A2/N	General disorders and administration site conditions/ Injection site rash/ SKIN RASH (INJECTION SITE: BUTTOCK)	25JUL2012 /41	04OCT2012 /-217	I	1	1	1	3	1
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	25JUL2012 /41	02APR2013 /-37	I	1	1	1	3	1
	Infections and infestations/ Fungal skin infection/ FUNGAL SKIN INFECTION	07FEB2013 /238	30APR2013 /-9	I	1	1	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	30MAY2013 /350	12JUN2013 /34	I	1	3	1	5 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0018/70 /M/A2/N	Gastrointestinal disorders/ Abdominal tenderness/ LEFT ABDOMINAL TENDERNESS	01OCT2012 /109	18OCT2012 /-203	I	1	1	1	5	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	04JUN2013 /355	18JUN2013 /40	C	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	19JUL2012 /35	24JUL2012 /-289	C	1	1	1	2	2
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH (ABDOMEN AND BUTTOCK)	19JUL2012 /35	24JUL2012 /-289	C	1	1	1	2	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0020/68 /F/A2/N	Gastrointestinal disorders/ Abdominal pain/ WORSENING OF ABDOMINAL PAIN	30OCT2012 /75	23MAR2013 /144	C	1	1	1	5	3
	Psychiatric disorders/ Insomnia/ WORSENING OF INSOMNIA	27AUG2012 /11	23MAR2013 /144	C	1	1	1	5	3
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	02OCT2012 /47	23MAR2013 /144	C	1	0	1	4	2
	General disorders and administration site conditions/ Disease progression/ WORSEN OF HEPATOCELLULAR CARCINOMA	12NOV2012 /88	24DEC2012 /55	C	3	1	1	5 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0020/68 /F/A2/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	09OCT2012 /54	23MAR2013 /144	I	1	1	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ WORSENING OF ANOREXIA	25SEP2012 /40	23MAR2013 /144	C	1	1	1	4	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	03SEP2012 /18	23MAR2013 /144	C	1	0	1	3	1
	Skin and subcutaneous tissue disorders/ Alopecia/ HAIR LOSS	03SEP2012 /18	23MAR2013 /144	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0020/68 /F/A2/N	Vascular disorders/ Hypertension/ HYPERTENSION	21AUG2012 /5	23MAR2013 /144	C	1	1	1	5	2
	Gastrointestinal disorders/ Ascites/ ASCITES	30OCT2012 /75	23MAR2013 /144	C	1	0	1	5	1
307-0022/60 /M/A2/Y	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	16FEB2013 /81	18MAR2013 /32	I	1	1	1	5	3
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	17DEC2012 /20	02JAN2013 /-43	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0022/60 /M/A2/Y	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	11MAR2013 /104	18APR2013 /63	C	1	1	1	5	2
	Skin and subcutaneous tissue disorders/ Rash pruritic/ PRURITIC SKIN RASH (GENERAL)	14JAN2013 /48	21MAR2013 /35	I	1	1	1	4	2
	General disorders and administration site conditions/ Pain/ MULTIPLE SORENESS (GENERAL)	30DEC2012 /33	21FEB2013 /7	I	1	1	1	4	1
	Nervous system disorders/ Dysgeusia/ DYSGEUSIA	17DEC2012 /20	18APR2013 /63	C	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0022/60 /M/A2/Y	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	17DEC2012 /20	18APR2013 /63	C	1	1	1	3	2
307-0025/68 /M/A2/N	General disorders and administration site conditions/ Oedema peripheral/ LEG EDEMA	25MAY2013 /158	25SEP2013 /118	I	1	1	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	25MAY2013 /158	25SEP2013 /118	C	1	1	1	5	1
	Gastrointestinal disorders/ Oesophageal varices haemorrhage/ ESOPHAGEAL VARICES HEMORRHAGE	16MAY2013 /149	20MAY2013 /-10	C	1	3	1	5 [CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0025/68 /M/A2/N	Gastrointestinal disorders/ Ascites/ ASCITES	25MAY2013 /158	25SEP2013 /118	C	1	1	1	5	1
	Immune system disorders/ Drug hypersensitivity/ DRUG ALLERGIC REACTION (OVER TRUNK AND HANDS)	20MAR2013 /92	21MAR2013 /-70	C	1	1	1	2	1
	Immune system disorders/ Drug hypersensitivity/ DRUG ALLERGIC REACTION (OVER TRUNK AND HANDS)	20MAR2013 /92	20MAR2013 /-71	C	2	1	1	2	2
	Nervous system disorders/ Dysgeusia/ DYSGEUSIA	27DEC2012 /9	01JUL2013 /32	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0026/65 /M/A2/Y	Gastrointestinal disorders/ Duodenal ulcer/ DUODENAL ULCER	24MAY2013 /148	09DEC2013 /188	C	1	1	1	5	1
	Investigations/ Weight decreased/ WEIGHT LOSS	26MAR2013 /89	09DEC2013 /188	I	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH	26MAR2013 /89	09APR2013 /-56	C	1	0	1	4	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	18JUN2013 /173	09DEC2013 /188	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0026/65 /M/A2/Y	Injury, poisoning and procedural complications/ Transfusion reaction/ BLOOD TRANSFUSION REACTION	20MAY2013 /144	20MAY2013 /-15	C	1	1	1	5	1
	Psychiatric disorders/ Anxiety/ ANXIETY	22MAY2013 /146	09DEC2013 /188	C	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	20MAY2013 /144	09DEC2013 /188	C	1	1	1	5	2
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	07MAY2013 /131	28MAY2013 /-7	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0026/65 /M/A2/Y	Gastrointestinal disorders/ Duodenal ulcer/ DUODENAL ULCERS	20MAY2013 /144	24MAY2013 /-11	C	2	1	1	5 [CD]	2
	General disorders and administration site conditions/ Malaise/ GENERAL MALAISE	24MAY2013 /148	09DEC2013 /188	C	1	0	1	5	2
	General disorders and administration site conditions/ Malaise/ GENERAL MALAISE	14MAY2013 /138	24MAY2013 /-11	C	2	0	3 /14MAY2013 /29MAY2013	5 [CD]	3
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	23APR2013 /117	09DEC2013 /188	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0026/65 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	23APR2013 /117	09DEC2013 /188	I	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN ITCH	16APR2013 /110	30APR2013 /-35	I	1	1	1	4	1
	Nervous system disorders/ Dizziness/ DIZZINESS	23APR2013 /117	04JUN2013 /0	C	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ GENERAL SORENESS OVER EXTREMITIES	05FEB2013 /40	11JUN2013 /7	I	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0026/65 /M/A2/Y	Nervous system disorders/ Headache/ HEADACHE	24JAN2013 /28	09DEC2013 /188	I	1	0	1	4	2
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ GENERAL SORENESS OVER EXTREMITIES	24JAN2013 /28	04FEB2013 /-120	I	1	1	1	3	1
	General disorders and administration site conditions/ Injection site reaction/ INJECTION SITE REACTION	09JAN2013 /13	11JUN2013 /7	I	1	0	1	2	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIGHT SHOULDER PAIN	15JAN2013 /19	11JUN2013 /7	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0030/53 /M/A2/Y	Gastrointestinal disorders/ Abdominal pain/ ABDONINAL PAIN	08APR2013 /33	31MAY2013 /25	C	1	1	1	5	3
	General disorders and administration site conditions/ Disease progression/ WORSENING OF HEPATOCELLULAR CARCINOMA	09MAY2013 /64	31MAY2013 /25	C	4	1	2	5 [PD]	5
	Gastrointestinal disorders/ Nausea/ NAUSEA	22APR2013 /47	29APR2013 /-7	I	1	0	1	5	1
	Gastrointestinal disorders/ Haemorrhoids/ HEMORRHIDS	22APR2013 /47	31MAY2013 /25	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0030/53 /M/A2/Y	Gastrointestinal disorders/ Ascites/ WORSENING OF ASCITES	08APR2013 /33	31MAY2013 /25	C	1	3	1	5	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	15MAR2013 /9	31MAY2013 /25	I	1	0	1	3	1
307-0031/60 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Hiccups/ HICCUP	29OCT2013 /228	19DEC2013 /35	I	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	10DEC2013 /270	13DEC2013 /29	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0031/60 /M/A2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	28NOV2013 /258	02DEC2013 /18	C	1	0	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITTING	26OCT2013 /225	19DEC2013 /35	C	1	1	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	26OCT2013 /225	19DEC2013 /35	C	1	1	1	5	1
	General disorders and administration site conditions/ Disease progression/ WORSENING OF HEPATOCELLULAR CARCINOMA	10DEC2013 /270	19DEC2013 /35	C	4	0	1	5 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0031/60 /M/A2/N	Gastrointestinal disorders/ Upper gastrointestinal haemorrhage/ UPPER GASTROINTESTINAL BLEEDING	06DEC2013 /266	19DEC2013 /35	C	1	3	1	5 [CD]	3
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	02DEC2013 /262	19DEC2013 /35	C	1	1	1	5 [PD]	3
	Gastrointestinal disorders/ Oesophageal varices haemorrhage/ ESOPHAGEAL VARICES HEMORRHAGE	25OCT2013 /224	01NOV2013 /-13	C	1	1	3 /31OCT2013 /07NOV2013	5 [CD]	3
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	26OCT2013 /225	01DEC2013 /17	C	2	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0031/60 /M/A2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	03SEP2013 /172	05SEP2013 /-70	I	1	0	1	5	1
	Vascular disorders/ Hypertension/ HYPERTENSION	04SEP2013 /173	19DEC2013 /35	I	1	1	1	5	2
	General disorders and administration site conditions/ Asthenia/ GENERAL WEAKNESS	30AUG2013 /168	13SEP2013 /-62	C	1	0	1	5	2
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	03SEP2013 /172	05SEP2013 /-70	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0031/60 /M/A2/N	Gastrointestinal disorders/ Abdominal distension/ WORSENING OF ABDOMINAL FULLNESS	24OCT2013 /223	19DEC2013 /35	C	1	3	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Pulmonary oedema/ PULMONARY EDEMA	07SEP2013 /176	13SEP2013 /-62	C	1	1	1	5	1
	Gastrointestinal disorders/ Ascites/ ASCITES	30AUG2013 /168	19DEC2013 /35	C	1	3	1	5	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	29AUG2013 /167	30AUG2013 /-76	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0031/60 /M/A2/N	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	09SEP2013 /178	17SEP2013 /-58	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	05SEP2013 /174	08SEP2013 /-67	C	2	1	1	5	2
	Renal and urinary disorders/ Urinary retention/ URINE RETENTION	20JUN2013 /97	27JUN2013 /-140	C	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ NON-CARDIAC RIGHT CHEST WALL TENDERNESS	04JUL2013 /111	19DEC2013 /35	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0031/60 /M/A2/N	General disorders and administration site conditions/ Chest discomfort/ NOT OTHERWISE SPECIFIED CHEST TIGHTNESS	27JUN2013 /104	04JUL2013 /-133	I	1	0	1	4	1
	Musculoskeletal and connective tissue disorders/ Flank pain/ LEFT SIDE FLANK PAIN	20JUN2013 /97	27JUN2013 /-140	C	1	0	1	4	1
	General disorders and administration site conditions/ Pain/ GENERAL SORENESS	25APR2013 /41	20JUN2013 /-147	I	1	1	1	3	1
	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LEGS EDEMA	30AUG2013 /168	13SEP2013 /-62	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0031/60 /M/A2/N	Hepatobiliary disorders/ Cholecystitis acute/ ACUTE CHOLECYSTITIS	30AUG2013 /168	18SEP2013 /-57	C	1	1	3 /05SEP2013 /17SEP2013	4[CD]	3
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	29AUG2013 /167	19DEC2013 /35	I	1	1	1	5	2
	General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE REACTION (PRURITIS)	25APR2013 /41	14NOV2013 /0	I	1	1	1	2	1
307-0032/74 /F/A2/N	Ear and labyrinth disorders/ Tinnitus/ TINNITUS	11APR2013 /0	11MAY2013 /2	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0032/74 /F/A2/N	General disorders and administration site conditions/ Disease progression/ WORSENING OF HEPATOCELLULAR CARCINOMA	11MAY2013 /30	11MAY2013 /2	C	4	0	1	5 [PD]	5
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	02MAY2013 /21	11MAY2013 /2	C	1	1	1	5	2
	Investigations/ Blood cholesterol increased/ CHOLESTEROL HIGH	02MAY2013 /21	11MAY2013 /2	C	1	0	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	18APR2013 /7	11MAY2013 /2	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0032/74 /F/A2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	18APR2013 /7	11MAY2013 /2	I	1	1	1	5	2
	Investigations/ Electrocardiogram QT prolonged/ ELECTROCARDIOGRAM QT CORRECTED INTERVAL PROLONGED	11APR2013 /0	18APR2013 /-21	C	1	0	1	4	2
307-0037/61 /M/A2/Y	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	12NOV2013 /40	18NOV2013 /38	C	1	0	1	5	2
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	12NOV2013 /40	06JAN2014 /87	C	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0037/61 /M/A2/Y	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	17OCT2013 /14	11NOV2013 /31	C	2	1	1	5	2
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	24OCT2013 /21	11NOV2013 /31	C	2	0	1	5	3
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	17OCT2013 /14	23OCT2013 /12	C	2	0	1	5	2
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	11OCT2013 /8	19APR2014 /190	C	1	1	2	4[CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0037/61 /M/A2/Y	General disorders and administration site conditions/ Fatigue/ FAITIGUE	11OCT2013 /8	14NOV2013 /34	I	1	0	1	3	1
307-0039/51 /M/A2/Y	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	27NOV2013 /22	11DEC2013 /-41	C	1	0	1	3	2
	Psychiatric disorders/ Insomnia/ INSOMNIA	23DEC2013 /48	16OCT2014 /268	C	1	1	1	5	2
	Investigations/ Blood creatinine increased/ INCREASED CREATININE	07JAN2014 /63	21JAN2014 /0	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0039/51 /M/A2/Y	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	07JAN2014 /63	21JAN2014 /0	C	1	1	1	3	1
307-0040/65 /M/A2/Y	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	01JUL2014 /35	08JUL2014 /14	C	2	0	1	5	3
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	01JUL2014 /35	08JUL2014 /14	C	2	1	1	5	3
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	01JUL2014 /35	08JUL2014 /14	C	2	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0040/65 /M/A2/Y	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	01JUL2014 /35	08JUL2014 /14	C	2	0	1	5	2
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	01JUL2014 /35	08JUL2014 /14	C	2	0	1	5	3
	Gastrointestinal disorders/ Ascites/ ASCITES	27JUN2014 /31	04AUG2014 /41	C	1	1	1	5	1
	Psychiatric disorders/ Anxiety/ ANXIETY	24JUN2014 /28	04AUG2014 /41	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0040/65 /M/A2/Y	Hepatobiliary disorders/ Hepatic failure/ HEPATIC FAILURE	08JUL2014 /42	04AUG2014 /41	C	4	1	1	5 [PD]	5
	Gastrointestinal disorders/ Upper gastrointestinal haemorrhage/ UPPER GASTROINTESTINAL BLEEDING	09JUL2014 /43	04AUG2014 /41	C	1	3	1	5 [CD]	3
	General disorders and administration site conditions/ Fatigue/ FATIGUE	01JUL2014 /35	04AUG2014 /41	C	1	1	3 /01JUL2014 /Unknown	4	3
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	28JUN2014 /32	Unknown/NA	C	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0040/65 /M/A2/Y	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	26JUN2014 /30	27JUN2014 /3	I	1	1	1	5	3
307-0043/54 /M/A2/N	Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	27OCT2014 /124	01NOV2014 /11	C	1	0	1	5	2
	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	27OCT2014 /124	01NOV2014 /11	C	1	1	1	5	2
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	21OCT2014 /118	01NOV2014 /11	C	1	0	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0043/54 /M/A2/N	Hepatobiliary disorders/ Hepatic failure/ HEPATIC FAILURE	27OCT2014 /124	01NOV2014 /11	C	4	1	2	5 [CD]	4
	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ CHEST WALL PAIN	14OCT2014 /111	01NOV2014 /11	C	1	1	1	5	2
	Psychiatric disorders/ Insomnia/ INSOMNIA	14OCT2014 /111	01NOV2014 /11	C	1	1	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	20AUG2014 /56	01NOV2014 /11	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0043/54 /M/A2/N	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH	05AUG2014 /41	26AUG2014 /-56	C	1	1	1	3	1
	Musculoskeletal and connective tissue disorders/ Chest wall mass/ RIGHT CHEST WALL MASS	05AUG2014 /41	01NOV2014 /11	C	1	0	1	5	1
307-0044/53 /M/A2/N	Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT HIP PAIN	27JUN2014 /0	11SEP2014 /69	I	1	1	1	5	2
	Infections and infestations/ Infection/ INFECTION CAUSE UNKNOWN	08JUL2014 /11	14JUL2014 /10	C	1	1	3 /10JUL2014 /Unknown	5[CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0044/53 /M/A2/N	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	04JUL2014 /7	07AUG2014 /34	C	1	0	1	5	2
307-0045/48 /M/A2/Y	Nervous system disorders/ Hyperammonaemic encephalopathy/ HYPERAMMONEMIC ENCEPHALOPATHY	19AUG2014 /43	25AUG2014 /-28	C	1	1	1	2	2
	Nervous system disorders/ Hyperammonaemic encephalopathy/ HYPERAMMONEMIC ENCEPHALOPATHY	08AUG2014 /32	12AUG2014 /-41	C	2	1	1	2	2
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	01AUG2014* /25	Unknown/NA	I	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0045/48 /M/A2/Y	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRAGLA	08SEP2014 /63	Unknown/NA	C	6	1	1	5	2
	Psychiatric disorders/ Insomnia/ INSOMNIA	28JUL2014 /21	Unknown/NA	I	6	1	1	5	2
	Nervous system disorders/ Hyperammonaemic encephalopathy/ HYPERAMMONEMIC ENCEPHALOPATHY	12AUG2014 /36	19AUG2014 /-34	C	1	1	3 /12AUG2014 /19AUG2014	2	3
	Nervous system disorders/ Hyperammonaemic encephalopathy/ HYPERAMMONEMIC ENCEPHALOPATHY	31JUL2014 /24	08AUG2014 /-45	C	1	1	3 /04AUG2014 /19AUG2014	2	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0045/48 /M/A2/Y	Metabolism and nutrition disorders/ Hyperammonaemia/ HYPERAMMONEMIA	20JUL2014 /13	30JUL2014 /-54	C	2	1	1	3	2
307-0046/46 /M/A2/Y	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	05AUG2014 /19	03NOV2014 /109	C	1	1	1	5	2
	Gastrointestinal disorders/ Stomatitis/ MUCOSITIS ORAL	04AUG2014 /18	12AUG2014 /26	I	1	1	1	5	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	27JUL2014 /10	13MAR2015 /239	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0046/46 /M/A2/Y	Gastrointestinal disorders/ Ascites/ ASCITES	23JUL2014 /6	13MAR2015 /239	C	1	3	1	5	3
	General disorders and administration site conditions/ Pyrexia/ FEVER	21JUL2014 /4	12AUG2014 /26	I	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	19JUL2014 /2	13MAR2015 /239	C	1	1	1	5	2
	Hepatobiliary disorders/ Hepatic haemorrhage/ HEPATIC HEMORRHAGE	19JUL2014 /2	12AUG2014 /26	C	1	3	2	5 [CD]	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0003/54 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	05NOV2013 /280	10DEC2013 /63	I	1	1	1	4	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	20AUG2013 /203	27AUG2013 /-42	I	1	1	1	4	1
	Gastrointestinal disorders/ Lower gastrointestinal haemorrhage/ LOWER GASTROINTESTINAL HEMORRHAGE	13AUG2013 /196	20AUG2013 /-49	I	1	2	1	5	1
	Musculoskeletal and connective tissue disorders/ Flank pain/ RIFHT FLANK AREA PAIN	08OCT2013 /252	10DEC2013 /63	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0003/54 /M/A2/N	Investigations/ Blood cholesterol increased/ CHOLESTEROL HIGH	08AUG2013 /191	15OCT2013 /7	C	1	1	3 /27AUG2013 /10SEP2013	4	4
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	03SEP2013 /217	17SEP2013 /-21	C	1	0	1	4	1
	Investigations/ Blood cholesterol increased/ CHOLESTEROL HIGH	15OCT2013 /259	10DEC2013 /63	C	1	1	1	4	3
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	25JUN2013 /147	01OCT2013 /-7	C	1	0	3 /27AUG2013 /10SEP2013	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0003/54 /M/A2/N	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	04JUN2013 /126	11JUN2013 /-119	C	1	0	3 /04JUN2013 /11JUN2013	4	1
	Investigations/ Blood cholesterol increased/ CHOLESTEROL HIGH	28MAY2013 /119	07AUG2013 /-62	C	1	1	3 /04JUN2013 /11JUN2013	4	3
	Psychiatric disorders/ Insomnia/ INSOMNIA	12MAR2013 /42	10DEC2013 /63	I	1	1	1	4	1
	Gastrointestinal disorders/ Vomiting/ VOMITTING	12MAR2013 /42	19MAR2013 /-203	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0003/54 /M/A2/N	General disorders and administration site conditions/ Malaise/ MALAISE	19FEB2013 /21	10DEC2013 /63	I	1	0	1	5	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	13FEB2013 /15	02APR2013 /-189	I	1	0	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	12MAR2013 /42	10DEC2013 /63	C	1	1	1	4	2
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	12MAR2013 /42	16APR2013 /-175	C	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0005/69 /F/A2/N	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	12AUG2013 /104	17AUG2013 /32	C	1	1	1	4	2
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	08AUG2013 /100	10SEP2013 /56	C	1	3	1	4	1
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	08AUG2013 /100	10SEP2013 /56	C	1	1	1	4	3
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	27JUL2013 /88	10SEP2013 /56	C	1	3	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0005/69 /F/A2/N	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRALGIA	27JUL2013 /88	10SEP2013 /56	C	1	1	1	5	2
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	08AUG2013 /100	10SEP2013 /56	C	1	1	1	4 [PD]	3
	Gastrointestinal disorders/ Nausea/ NAUSEA	25MAY2013 /25	10SEP2013 /56	I	1	1	1	5	2
	Gastrointestinal disorders/ Gastrooesophageal reflux disease/ REFLUX ESOPHAGITIS	11JUN2013 /42	10SEP2013 /56	C	1	3	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0005/69 /F/A2/N	Investigations/ Eosinophil count increased/ EOSINOPHILS INCREASED	02JUL2013 /63	10SEP2013 /56	C	1	0	1	2	1
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	02JUL2013 /63	10SEP2013 /56	C	1	1	1	5	2
	Gastrointestinal disorders/ Peptic ulcer/ PEPTIC ULCER	11JUN2013 /42	10SEP2013 /56	C	1	1	1	4	2
	General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE ITCHING	30APR2013 /0	10SEP2013 /56	C	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0001/46 /M/A2/N	Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE SORENESS	02JUL2012 /20	24SEP2012 /34	I	1	0	1	3	1
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	25JUN2012 /13	24SEP2012 /34	C	1	0	1	3	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	13SEP2012 /93	21JAN2013 /153	I	1	0	1	5	2
	Skin and subcutaneous tissue disorders/ Palmar-plantar erythrodysaesthesia syndrome/ HAND FOOT SYNDROME	15SEP2012 /95	21JAN2013 /153	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0002/56 /M/A2/N	General disorders and administration site conditions/ Non-cardiac chest pain/ NON-CARDIAC TENDERNESS OVER STERNUM AREA	20JUN2012 /7	13AUG2012 /54	I	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ RIGHT CHEST WALL PAIN	10JUL2012 /27	20AUG2012 /61	I	1	0	1	5	1
	Injury, poisoning and procedural complications/ Skin abrasion/ ABRASIONS WOUNDS WITH RIGHT FOOT	10JUL2012 /27	17AUG2012 /58	C	1	1	1	5	2
	General disorders and administration site conditions/ Asthenia/ WEAKNESS	16JUL2012 /33	27OCT2012 /129	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0003/52 /F/A2/N	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	23JUN2012 /3	28JUN2012 /-62	C	1	1	3 /27JUN2012 /04JUL2012	3	3
	Gastrointestinal disorders/ Ascites/ ASCITES	24JUN2012 /4	29JAN2013 /153	C	1	1	1	5	2
	Nervous system disorders/ Headache/ HEADACHE	24AUG2012 /65	05SEP2012 /7	I	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	24AUG2012 /65	05SEP2012 /7	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0003/52 /F/A2/N	Skin and subcutaneous tissue disorders/ Alopecia/ ALOPECIA	16AUG2012 /57	29JAN2013 /153	I	1	0	1	4	1
	General disorders and administration site conditions/ Injection site pruritus/ SKIN PRURITUS OVER INJECTION SITE	01AUG2012 /42	22AUG2012 /-7	I	1	1	1	3	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ BILATERAL ANKLE PAIN	30JUL2012 /40	29AUG2012 /0	C	1	1	1	5	1
	General disorders and administration site conditions/ Asthenia/ GENERAL WEAKNESS	26JUN2012 /6	29JAN2013 /153	I	1	0	3 /18JUL2012 /25JUL2012	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0003/52 /F/A2/N	Gastrointestinal disorders/ Vomiting/ VOMITING	15JUL2012 /25	16JUL2012 /-44	I	1	0	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	06JUL2012 /16	31OCT2012 /63	I	1	0	1	3	1
309-0004/55 /M/A2/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	26JUN2012 /1	19JUL2012 /16	I	1	1	1	3	1
	Renal and urinary disorders/ Haematuria/ WORSENING OF HEMATURIA	26JUN2012 /1	27JUN2012 /-6	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0004/55 /M/A2/Y	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	29JUN2012 /4	05JUL2012 /2	I	1	1	1	5	1
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ DISEASE PROGRESSION OF MALIGNANCY	19JUL2012 /24	19JUL2012 /16	C	4	0	1	5 [PD]	5
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	17JUL2012 /22	19JUL2012 /16	C	1	1	1	5 [PD]	4
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	15JUL2012 /20	19JUL2012 /16	C	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0004/55 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ SNUFFLE	14JUL2012 /19	14JUL2012 /11	I	1	1	1	5	1
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	10JUL2012 /15	19JUL2012 /16	C	1	0	1	5 [PD]	4
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	05JUL2012 /10	19JUL2012 /16	I	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Hiccups/ HICCUPS	06JUL2012 /11	19JUL2012 /16	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0004/55 /M/A2/Y	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	03JUL2012 /8	10JUL2012 /7	C	1	0	1	5	3
	General disorders and administration site conditions/ Oedema peripheral/ LEG EDEMA	01JUL2012 /6	19JUL2012 /16	C	1	1	1	5	1
	Investigations/ White blood cell count increased/ WHITE BLOOD COUNT INCREASED	27JUN2012 /2	02JUL2012 /-1	C	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ LEFT RIB PAIN	28JUN2012 /3	28JUN2012 /-5	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0004/55 /M/A2/Y	Gastrointestinal disorders/ Cheilitis/ ANGULAR CHEILITIS	01JUL2012 /6	19JUL2012 /16	C	1	1	1	5	1
	Gastrointestinal disorders/ Oesophageal varices haemorrhage/ ESOPHAGEAL VARICES BLEEDING	27JUN2012 /2	19JUL2012 /16	I	1	3	1	3	3
309-0008/38 /M/A2/N	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	09MAY2013 /77	31DEC2013 /243	C	1	0	1	4	1
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	09MAY2013 /77	26DEC2013 /238	C	1	0	1	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0008/38 /M/A2/N	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	09MAY2013 /77	26DEC2013 /238	C	1	0	1	3	3
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	25APR2013 /63	09MAY2013 /7	C	1	0	1	3	2
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	25APR2013 /63	09MAY2013 /7	C	1	0	1	3	2
	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN PRURITUS OVER BILATERAL UPPER ARM	02MAR2013 /9	21MAR2013 /-42	C	1	1	1	2	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0008/38 /M/A2/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	02MAR2013 /9	14MAR2013 /-49	I	1	1	1	5	2
309-0010/47 /M/A2/Y	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	06APR2013 /12	12APR2013 /-556	C	1	1	3 /10APR2013 /15APR2013	3	3
	Nervous system disorders/ Dizziness/ DIZZINESS	24MAR2014 /364	31MAR2014 /-203	I	1	0	1	5	1
	Gastrointestinal disorders/ Haemorrhoids/ HEMORRHOID	24OCT2013 /213	10FEB2014 /-252	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0010/47 /M/A2/Y	Gastrointestinal disorders/ Gastrooesophageal reflux disease/ REFLUX ESOPHAGITIS	18SEP2013 /177	Unknown/NA	C	6	0	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN PRURITUS	21OCT2013 /210	24NOV2014 /35	I	1	1	1	2	2
	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN PRURITUS	14OCT2013 /203	15OCT2013 /-370	C	1	0	1	3	2
	Gastrointestinal disorders/ Haemorrhoids/ WORSENING OF HEMORRHOID	16SEP2013 /175	23OCT2013 /-362	I	2	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0010/47 /M/A2/Y	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	10JUN2013 /77	19AUG2013 /-427	C	1	1	1	5	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	01JUL2013 /98	10MAR2014 /-224	C	1	1	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ WORSENING OF ANEMIA	27MAY2013 /63	10JUN2013 /-497	C	2	2	1	5	3
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	29APR2013 /35	27MAY2013 /-511	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0010/47 /M/A2/Y	Blood and lymphatic system disorders/ Anaemia/ WORSENING OF ANEMIA	22APR2013 /28	29APR2013 /-539	C	2	2	1	5	3
	Respiratory, thoracic and mediastinal disorders/ Epistaxis/ EPISTAXIS	08APR2013 /14	08APR2013 /-560	I	1	1	1	5	2
309-0011/59 /M/A2/Y	Skin and subcutaneous tissue disorders/ Pruritus/ WORSENING OF SKIN PRURITUS	15APR2013 /7	02JUL2013 /15	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	30JUN2013 /83	02JUL2013 /15	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0011/59 /M/A2/Y	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	30JUN2013 /83	02JUL2013 /15	C	1	1	1	5	2
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	30JUN2013 /83	02JUL2013 /15	C	1	1	1	5	4
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	23JUN2013 /76	02JUL2013 /15	C	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT NEOPLASM PROGRESSION	24JUN2013 /77	02JUL2013 /15	C	4	1	1	5[(Discharg e Against Medical Advice) Was Arranged Under The Family's Request On 02-Jul-2013 .He Was Death On 02-Jul-2013 Due To Malignant Neoplasm Progression .]	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0011/59 /M/A2/Y	Metabolism and nutrition disorders/ Hypoglycaemia/ HYPOGLYCEMIA	22JUN2013 /75	23JUN2013 /6	I	1	1	1	5 [CD]	4
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	23JUN2013 /76	02JUL2013 /15	C	1	0	1	5	2
	Investigations/ C-reactive protein increased/ C-REACTIVE PROTEIN INCREASED	23JUN2013 /76	02JUL2013 /15	C	1	1	1	5	2
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	10JUN2013 /63	30JUN2013 /13	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0011/59 /M/A2/Y	Investigations/ Blood creatinine increased/ CREATININE INCREASED	10JUN2013 /63	24JUN2013 /7	C	1	0	1	5	2
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	10JUN2013 /63	23JUN2013 /6	C	1	0	1	5	2
	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	10JUN2013 /63	02JUL2013 /15	C	1	0	1	5	2
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	10JUN2013 /63	30JUN2013 /13	C	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0012/82 /M/A2/N	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	06JUN2013 /14	13JUN2013 /-49	C	1	1	1	2	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	20AUG2013 /89	31DEC2013 /152	C	1	0	1	5	1
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	27JUN2013 /35	02SEP2013 /32	C	1	0	1	4	1
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	02SEP2013 /102	31DEC2013 /152	C	1	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0012/82 /M/A2/N	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	02SEP2013 /102	31DEC2013 /152	C	1	0	1	4	3
	Gastrointestinal disorders/ Abdominal pain/ LEFT ABDOMINAL PAIN	08AUG2013 /77	31DEC2013 /152	I	1	1	1	5	2
	General disorders and administration site conditions/ Malaise/ MALAISE	08AUG2013 /77	31DEC2013 /152	C	1	0	1	5	2
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	25JUL2013 /63	08AUG2013 /7	C	1	1	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0012/82 /M/A2/N	General disorders and administration site conditions/ Injection site erythema/ BILATERAL ARM INJECTION SITE REDNESS	04JUL2013 /42	08AUG2013 /7	C	1	1	1	2	2
	General disorders and administration site conditions/ Injection site erythema/ BILATERAL ARM INJECTION SITE REDNESS	27JUN2013 /35	03JUL2013 /-29	C	1	0	1	2	1
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	13JUN2013 /21	27JUN2013 /-35	C	2	0	1	3	2
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	13JUN2013 /21	02SEP2013 /32	C	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0012/82 /M/A2/N	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LEG EDEMA	10JUN2013 /18	03DEC2013 /124	C	1	1	1	4	1
309-0015/62 /M/A2/Y	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ CHEST WALL SORENESS	24JUN2013 /0	01JUL2013 /-63	I	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Spinal osteoarthritis/ SPONDYLOSIS OF LUMBAR-SPINE	20SEP2013 /88	20MAY2014 /260	C	1	0	1	5	1
	Gastrointestinal disorders/ Toothache/ TOOTH PAIN	18SEP2013 /86	18SEP2013 /16	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0015/62 /M/A2/Y	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	24SEP2013 /92	03OCT2013 /31	I	1	1	1	5	2
	Gastrointestinal disorders/ Varices oesophageal/ ESOPHAGEAL VARICES	12AUG2013 /49	20MAY2014 /260	C	1	1	1	5	2
	Gastrointestinal disorders/ Duodenal ulcer/ DUODENAL ULCERS	12AUG2013 /49	20MAY2014 /260	C	1	1	1	5	2
	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN ITCH WITH BILATERAL ARM	12AUG2013 /49	02SEP2013 /0	I	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0015/62 /M/A2/Y	Gastrointestinal disorders/ Constipation/ CONSTIPATION	15JUL2013 /21	20MAY2014 /260	I	1	1	1	5	2
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	24JUN2013 /0	15JUL2013 /-49	I	1	1	1	5	1
309-0016/72 /F/A2/N	Psychiatric disorders/ Insomnia/ INSOMNIA	05DEC2013 /91	14JAN2014 /61	I	1	1	1	5	2
	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN ITCH	15NOV2013 /71	04DEC2013 /20	I	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0016/72 /F/A2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	31OCT2013 /56	14JAN2014 /61	I	1	1	1	4	2
	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	14NOV2013 /70	14JAN2014 /61	I	1	1	1	5	1
	Gastrointestinal disorders/ Ascites/ ASCITES	07NOV2013 /63	14JAN2014 /61	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	31OCT2013 /56	14JAN2014 /61	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0016/72 /F/A2/N	General disorders and administration site conditions/ Injection site pruritus/ SKIN ITCH AT INJECTION SITE	09SEP2013 /4	18SEP2013 /-57	I	1	1	1	3	2
309-0017/73 /F/A2/Y	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ PAIN OF BOTH SHOULDER	06JAN2014 /35	26JUN2014 /136	I	1	1	1	5	2
	Infections and infestations/ Carbuncle/ CARBUNCLE OVER SCALP	20FEB2014 /80	17MAR2014 /35	C	1	1	1	5	2
	Eye disorders/ Trichiasis/ TRICHIASIS OF OCULUS UTERQUE	06MAR2014 /94	06MAR2014 /24	C	1	3	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0017/73 /F/A2/Y	Metabolism and nutrition disorders/ Diabetes mellitus/ WORSENING OF DIABETES MELLITUS TYPE II	11FEB2014 /71	17FEB2014 /7	I	1	1	1	5	3
	Infections and infestations/ Carbuncle/ CARBUNCLE OVER SCALP	10FEB2014 /70	20FEB2014 /10	C	2	3	1	5	3
	Infections and infestations/ Carbuncle/ CARBUNCLE OVER SCALP	29JAN2014 /58	10FEB2014 /0	C	1	0	1	5	2
	Nervous system disorders/ Dizziness/ DIZZINESS	06JAN2014 /35	17MAR2014 /35	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0017/73 /F/A2/Y	Psychiatric disorders/ Insomnia/ INSOMNIA	06JAN2014 /35	26JUN2014 /136	I	1	1	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ WORSENING OF BILATERAL LEG EDEMA	09DEC2013 /7	15APR2014 /64	C	1	1	1	5	2
309-0018/82 /M/A2/Y	General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	30JUN2014 /14	28JUL2014 /-28	I	1	0	1	2	1
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	25SEP2014 /101	28OCT2014 /64	C	1	0	1	5	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0018/82 /M/A2/Y	Gastrointestinal disorders/ Abdominal distension/ ABDOMONAL DISTENSION	25AUG2014 /70	28OCT2014 /64	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	25SEP2014 /101	28OCT2014 /64	C	1	1	1	5	2
	Gastrointestinal disorders/ Ascites/ ASCITES	25SEP2014 /101	28OCT2014 /64	C	1	3	1	5	3
	Gastrointestinal disorders/ Ascites/ ASCITES	25AUG2014 /70	25SEP2014 /31	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0018/82 /M/A2/Y	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	18AUG2014 /63	25SEP2014 /31	C	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ NON-CARDIAC RIGHT CHEST WALL PAIN	11AUG2014 /56	25SEP2014 /31	I	1	1	1	4	2
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	04AUG2014 /49	25SEP2014 /31	C	1	0	1	4	1
	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LEG EDEMA	04AUG2014 /49	28OCT2014 /64	I	1	3	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0018/82 /M/A2/Y	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LEG EDEMA	28JUL2014 /42	04AUG2014 /-21	I	1	1	1	4	1
309-0021/54 /F/A2/N	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	02OCT2014 /77	28NOV2014 /78	C	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ BLOODY SPUTUM	02OCT2014 /77	19NOV2014 /69	I	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	02OCT2014 /77	28NOV2014 /78	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0021/54 /F/A2/N	General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE ITCHING	04SEP2014 /49	16OCT2014 /35	I	1	1	1	1	1
	Respiratory, thoracic and mediastinal disorders/ Nasal polyps/ NASAL POLYPS	28AUG2014 /42	16OCT2014 /35	C	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	21AUG2014 /35	28NOV2014 /78	I	1	1	1	3	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	14AUG2014 /28	28NOV2014 /78	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0021/54 /F/A2/N	General disorders and administration site conditions/ Injection site erythema/ INJECTION SITE REDNESS	01AUG2014 /15	28AUG2014 /-14	I	1	1	1	1	1
	General disorders and administration site conditions/ Oedema peripheral/ LEG EDEMA	07AUG2014 /21	21AUG2014 /-21	I	1	1	1	5	1
309-0025/49 /M/A2/N	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT NEOPLASM PROGRESSION	01SEP2014 /7	04SEP2014 /3	C	1	0	1	5	2
	Metabolism and nutrition disorders/ Hypoglycaemia/ HYPOGLYCEMIA	04SEP2014 /10	04SEP2014 /3	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0025/49 /M/A2/N	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT NEOPLASM PROGRESSION	04SEP2014 /10	04SEP2014 /3	C	4	0	1	5 [PD]	5
	Infections and infestations/ Pneumonia/ PNEUMONIA	03SEP2014 /9	04SEP2014 /3	C	1	3	1	5 [PD]	3
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORT OF BREATHING	31AUG2014 /6	04SEP2014 /3	C	1	3	1	5	3
	Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT SORENESS	25AUG2014 /0	04SEP2014 /3	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0026/41 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	22SEP2014 /0	15FEB2015 /19	I	1	0	1	5	2
	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN ITCHING	05FEB2015 /136	10FEB2015 /14	C	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ WORSENING OF ABDOMINAL PAIN	23JAN2015 /123	15FEB2015 /19	C	1	1	1	5	3
	Metabolism and nutrition disorders/ Hypoglycaemia/ HYPOGLYCEMIA	13FEB2015 /144	15FEB2015 /19	I	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0026/41 /M/A2/Y	Gastrointestinal disorders/ Mouth ulceration/ ORAL ULCERS	14FEB2015 /145	15FEB2015 /19	C	1	1	1	5	1
	Eye disorders/ Dry eye/ DRY EYE	14FEB2015 /145	15FEB2015 /19	I	1	1	1	5	1
	Metabolism and nutrition disorders/ Hypoglycaemia/ HYPOGLYCEMIA	11FEB2015 /142	12FEB2015 /16	I	2	1	1	5	4
	Psychiatric disorders/ Insomnia/ INSOMNIA	27JAN2015 /127	15FEB2015 /19	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0026/41 /M/A2/Y	Injury, poisoning and procedural complications/ Allergic transfusion reaction/ BOLLD TRANSFUSION ALLERGY	30JAN2015 /130	30JAN2015 /3	I	1	0	1	5	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	26JAN2015 /126	15FEB2015 /19	I	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ WORSENING OF RIGHT PLEURAL EFFUSION	22JAN2015 /122	15FEB2015 /19	C	1	3	1	5 [CD]	3
	Injury, poisoning and procedural complications/ Allergic transfusion reaction/ BLOOD TRANSFUSION ALLERGY	30DEC2014 /99	05JAN2015 /-22	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0026/41 /M/A2/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	24NOV2014 /63	15FEB2015 /19	I	1	1	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ WORSENING OF POOR APPETITE	19JAN2015 /119	15FEB2015 /19	C	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ RIGHT PLEURAL EFFUSION	08JAN2015 /108	21JAN2015 /-6	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	05JAN2015 /105	19JAN2015 /-8	C	1	0	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0026/41 /M/A2/Y	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	19NOV2014 /58	24NOV2014 /-64	C	1	0	1	5	3
	Injury, poisoning and procedural complications/ Inflammation of wound/ PIG-TAIL WOUND INFLAMMATION	31DEC2014 /100	12JAN2015 /-15	C	1	1	1	5	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	04JAN2015 /104	19JAN2015 /-8	I	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ ANKLE PAIN	31DEC2014 /100	15FEB2015 /19	I	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0026/41 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Pulmonary congestion/ PULMONARY CONGESTION	05JAN2015 /105	22JAN2015 /-5	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Pneumothorax/ RIGHT HYDROPNEUMOTHORAX	31DEC2014 /100	15FEB2015 /19	C	1	2	1	5	2
	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN ITCHING	29DEC2014 /98	12JAN2015 /-15	I	1	1	1	5	1
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	28DEC2014 /97	05JAN2015 /-22	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0026/41 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ WORSENING OF RIGHT PLEURAL EFFUSION	28DEC2014 /97	07JAN2015 /-20	C	2	3	1	5 [CD]	3
	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	09NOV2014 /48	10NOV2014 /-78	C	1	0	1	5	3
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ RIGHT PLEURAL EFFUSION	22NOV2014 /61	27DEC2014 /-31	C	1	1	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LOWER LEG EDEMA	24NOV2014 /63	15FEB2015 /19	C	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0026/41 /M/A2/Y	Gastrointestinal disorders/ Diarrhoea/ INTERMITTENT DIARRHEA	22NOV2014 /61	01DEC2014 /-57	I	1	1	1	5	1
	Infections and infestations/ Sepsis/ SEPSIS	19NOV2014 /58	01DEC2014 /-57	C	1	1	1	5	4
	Musculoskeletal and connective tissue disorders/ Exostosis/ SPURS FORMATION OF T-SPINE	19NOV2014 /58	15FEB2015 /19	C	1	0	1	5	1
	Eye disorders/ Dry eye/ DRY EYE	19NOV2014 /58	22DEC2014 /-36	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0026/41 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Emphysema/ EMPHYSEMATOUS OF BOTH LUNGS	07NOV2014 /46	10NOV2014 /-78	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Pneumothorax/ HYDROPNEUMOTHORAX	07NOV2014 /46	28DEC2014 /-30	C	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Petechiae/ PETECHIAE OF HAND	16NOV2014 /55	24NOV2014 /-64	I	1	1	1	5	1
	Gastrointestinal disorders/ Oral disorder/ ORAL LESIONS	16NOV2014 /55	24NOV2014 /-64	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0026/41 /M/A2/Y	Skin and subcutaneous tissue disorders/ Eczema/ ECZEMA OF PENIS	15NOV2014 /54	01DEC2014 /-57	I	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ WORSENING OF RIGHT PLEURAL EFFUSION	01NOV2014 /40	22NOV2014 /-66	C	2	3	1	5 [CD]	3
	Infections and infestations/ Gastroenteritis/ ACUTE GASTROENTERITIS	01NOV2014 /40	03NOV2014 /-85	I	1	1	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LOWER LEG EDEMA	25OCT2014 /33	24NOV2014 /-64	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0026/41 /M/A2/Y	Renal and urinary disorders/ Haematuria/ HEMATURIA	20OCT2014 /28	21OCT2014 /-98	I	1	1	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LOWER LEG EDEMA	10OCT2014 /18	15OCT2014 /-104	I	1	1	1	5	2
	Gastrointestinal disorders/ Gastritis/ ERYTHEMATOUS GASTRITIS	29SEP2014 /7	15FEB2015 /19	C	1	1	1	5	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENTION	22SEP2014 /0	15FEB2015 /19	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0030/33 /M/A2/Y	Hepatobiliary disorders/ Hepatic cirrhosis/ LIVER CIRRHOSIS	08FEB2015 /55	20FEB2015 /18	C	1	0	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITTING	19FEB2015 /66	20FEB2015 /18	I	1	1	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN ITCH	17FEB2015 /64	20FEB2015 /18	I	1	1	1	5	1
	Gastrointestinal disorders/ Mouth ulceration/ ORAL ULCERS	13FEB2015 /60	15FEB2015 /13	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0030/33 /M/A2/Y	Injury, poisoning and procedural complications/ Penis injury/ SCRAPE OF PENIS	12FEB2015 /59	13FEB2015 /11	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	16FEB2015 /63	20FEB2015 /18	C	1	1	1	5	2
	Hepatobiliary disorders/ Gallbladder polyp/ GALLBLADDER POLYP	13FEB2015 /60	20FEB2015 /18	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ BILATERAL PLEURAL EFFUSION	08FEB2015 /55	20FEB2015 /18	C	1	3	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0030/33 /M/A2/Y	Gastrointestinal disorders/ Ascites/ WORSENING OF ASCITES	16FEB2015 /63	20FEB2015 /18	C	1	3	1	5	3
	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	16FEB2015 /63	19FEB2015 /17	C	1	1	1	5	1
	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	16FEB2015 /63	20FEB2015 /18	C	1	0	1	5	3
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT NEOPLASM PROGRESSION	08FEB2015 /55	20FEB2015 /18	C	4	3	2	5 [PD]	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0030/33 /M/A2/Y	Gastrointestinal disorders/ Ascites/ WORSENING OF ASCITES	29JAN2015 /45	16FEB2015 /14	C	1	3	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	02FEB2015 /49	20FEB2015 /18	C	1	1	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LEG EDEMA	29JAN2015 /45	20FEB2015 /18	C	1	1	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LEG EDEMA	12JAN2015 /28	15JAN2015 /-18	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0030/33 /M/A2/Y	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN ITCH	23DEC2014 /8	12JAN2015 /-21	I	1	1	1	1	2
309-0031/34 /M/A2/Y	Gastrointestinal disorders/ Abdominal pain/ INTERMITTENT ABDOMINAL PAIN	15JAN2015 /21	03APR2015 /36	I	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	10MAR2015 /75	03APR2015 /36	I	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	15JAN2015 /21	20JAN2015 /-37	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0031/34 /M/A2/Y	Skin and subcutaneous tissue disorders/ Decubitus ulcer/ BED SORE	30MAR2015 /95	03APR2015 /36	C	1	2	1	5	2
	Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	30MAR2015 /95	03APR2015 /36	C	1	1	1	5	3
	General disorders and administration site conditions/ Pyrexia/ FEVER	30MAR2015 /95	30MAR2015 /32	I	1	1	1	5	1
	Skin and subcutaneous tissue disorders/ Ecchymosis/ ECCHYMOSES	26MAR2015 /91	03APR2015 /36	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0031/34 /M/A2/Y	General disorders and administration site conditions/ Non-cardiac chest pain/ CHEST PAIN -NO CARDIAC	11MAR2015 /76	03APR2015 /36	I	1	0	1	5	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	17FEB2015 /54	03APR2015 /36	I	1	1	1	5	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	08MAR2015 /73	03APR2015 /36	I	1	1	1	5	2
	Gastrointestinal disorders/ Ascites/ ASCITES	05MAR2015 /70	03APR2015 /36	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0031/34 /M/A2/Y	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	26FEB2015 /63	03APR2015 /36	C	1	0	1	5	3
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT NEOPLASM PROGRESSION	06MAR2015 /71	03APR2015 /36	C	4	3	1	5 [PD]	3
	Musculoskeletal and connective tissue disorders/ Muscular weakness/ BILATERAL LOW LEG WEAKNESS	01MAR2015 /66	03APR2015 /36	C	1	3	1	5	3
	Musculoskeletal and connective tissue disorders/ Muscular weakness/ RIGHT LEG WEAKNESS	24FEB2015 /61	01MAR2015 /3	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0031/34 /M/A2/Y	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	17FEB2015 /54	03APR2015 /36	C	1	1	1	5	2
	Investigations/ Blood cholesterol increased/ TOTAL CHOLESTEROL INCREASED	12FEB2015 /49	03APR2015 /36	C	1	1	3 /05MAR2015 /Unknown	3	4
	Vascular disorders/ Hypertension/ HYPERTENSION	27JAN2015 /33	03APR2015 /36	C	1	1	1	3	2
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	05FEB2015 /42	03APR2015 /36	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0031/34 /M/A2/Y	Investigations/ Blood cholesterol increased/ TOTAL CHOLESTEROL INCREASED	29JAN2015 /35	12FEB2015 /-14	C	1	0	1	3	3
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	29JAN2015 /35	26FEB2015 /0	C	1	0	1	5	2
	Nervous system disorders/ Headache/ HEADACHE	24JAN2015 /30	03APR2015 /36	I	1	1	1	4	1
309-0032/63 /M/A2/Y	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH OVER BILATERAL LEGS	23JAN2015 /15	04MAR2015 /-13	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0032/63 /M/A2/Y	Gastrointestinal disorders/ Gastric varices/ GASTRIC VARICES	19MAR2015 /70	30MAR2015 /13	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ RIGHT PLEURAL EFFUSION	19MAR2015 /70	30MAR2015 /13	I	1	3	1	5	3
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	29JAN2015 /21	12FEB2015 /-33	C	1	0	1	3	1
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	26MAR2015 /77	30MAR2015 /13	C	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0032/63 /M/A2/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT NEOPLASM PROGRESSION	27MAR2015 /78	30MAR2015 /13	C	4	3	1	5 [PD]	3
	Gastrointestinal disorders/ Ascites/ ASCITES	19MAR2015 /70	30MAR2015 /13	C	1	1	1	5	2
	Investigations/ Hepatic enzyme increased/ LIVER ENZYME INCREASED	12MAR2015 /63	30MAR2015 /13	I	1	0	1	5	3
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	17MAR2015 /68	30MAR2015 /13	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0032/63 /M/A2/Y	General disorders and administration site conditions/ Malaise/ MALAISE	17MAR2015 /68	30MAR2015 /13	C	1	0	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	05MAR2015 /56	30MAR2015 /13	C	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	26FEB2015 /49	30MAR2015 /13	I	1	1	1	5	2
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	05FEB2015 /28	12FEB2015 /-33	C	1	0	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0032/63 /M/A2/Y	Gastrointestinal disorders/ Vomiting/ VOMITTING	07FEB2015 /30	08FEB2015 /-37	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	05FEB2015 /28	30MAR2015 /13	I	1	1	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LEG EDEMA	01FEB2015 /24	30MAR2015 /13	C	1	3	1	5	2
	Musculoskeletal and connective tissue disorders/ Back pain/ LOW BACK PAIN	29JAN2015 /21	30MAR2015 /13	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0033/78 /F/A2/N	Nervous system disorders/ Coma hepatic/ HEPATIC COMA	10FEB2015 /12	26FEB2015 /-126	C	1	1	1	5[CD]	3
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	25JUN2015 /147	Unknown/NA	C	6	0	1	5	2
	Renal and urinary disorders/ Nocturia/ NOCTURIA	02JUL2015 /154	Unknown/NA	I	6	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	17JUN2015 /139	Unknown/NA	I	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0033/78 /F/A2/N	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ LEFT SHOULDER PAIN	05JUN2015 /127	Unknown/NA	I	6	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Gouty arthritis/ GOUTY ARTHROPATHY	11JUN2015 /133	Unknown/NA	I	6	1	1	2	2
	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LEG EDEMA	04JUN2015 /126	Unknown/NA	I	6	1	1	5	1
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	14MAY2015 /105	28MAY2015 /-35	C	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0033/78 /F/A2/N	Respiratory, thoracic and mediastinal disorders/ Asthma/ ASTHMA	14MAY2015 /105	Unknown/NA	I	6	1	1	5	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	21MAY2015 /112	Unknown/NA	I	6	1	1	5	2
	Skin and subcutaneous tissue disorders/ Dry skin/ SKIN DRYNESS	30APR2015 /91	Unknown/NA	I	6	1	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN ITCH	23APR2015 /84	Unknown/NA	I	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0033/78 /F/A2/N	Nervous system disorders/ Dementia/ DEMENTIA	17MAR2015 /47	Unknown/NA	C	6	0	1	5	2
	Reproductive system and breast disorders/ Vaginal haemorrhage/ VAGINAL SPOTTING	20MAR2015 /50	15APR2015 /-78	I	1	1	1	5	2
	Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	20MAR2015 /50	Unknown/NA	C	6	1	1	5	2
	Endocrine disorders/ Adrenal disorder/ DIFFUSE CORTICAL DYSFUNCTION	17MAR2015 /47	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0033/78 /F/A2/N	Endocrine disorders/ Hypothyroidism/ HYPOTHYROIDISM	05MAR2015 /35	Unknown/NA	C	6	1	1	5	2
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	05MAR2015 /35	18JUN2015 /-14	I	1	1	1	5	3
	Infections and infestations/ Sepsis/ SEPSIS	11FEB2015 /13	26FEB2015 /-126	C	1	1	1	5	4
	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LEG EDEMA	11FEB2015 /13	21MAY2015 /-42	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0033/78 /F/A2/N	Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	12FEB2015 /14	16FEB2015 /-136	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	15FEB2015 /17	17FEB2015 /-135	C	1	0	1	5	3
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	11FEB2015 /13	15FEB2015 /-137	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	11FEB2015 /13	11FEB2015 /-141	C	2	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0033/78 /F/A2/N	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	10FEB2015 /12	11FEB2015 /-141	C	1	1	1	5	2
310-0001/61 /M/A2/N	Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIA	22AUG2012 /64	01JUN2013 /291	I	1	1	1	5	2
	Renal and urinary disorders/ Dysuria/ DYSFUNCTIONAL VOIDING	06SEP2012 /79	07SEP2012 /24	I	1	1	1	5	1
	Nervous system disorders/ Hypoaesthesia/ BILATERAL PLANTAR NUMBNESS	29AUG2012 /71	01JUN2013 /291	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0001/61 /M/A2/N	Injury, poisoning and procedural complications/ Wound haemorrhage/ SURGICAL WOUND BLEEDING	29AUG2012 /71	31AUG2012 /17	C	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	31AUG2012 /73	06SEP2012 /23	I	1	1	1	5	2
	Injury, poisoning and procedural complications/ Wound complication/ SURGICAL WOUND PAIN	31AUG2012 /73	31AUG2012 /17	I	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Muscular weakness/ BILATERAL LEG WEAKNESS	24JUL2012 /35	01JUN2013 /291	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0001/61 /M/A2/N	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	31JUL2012 /42	01JUN2013 /291	I	1	0	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ WORSENING ANEMIA	10JUL2012 /21	01JUN2013 /291	C	1	0	1	3	2
	Gastrointestinal disorders/ Gingival swelling/ SWELLING OF GUM	03JUL2012 /14	10JUL2012 /-35	I	1	1	1	5	1
310-0002/55 /M/A2/Y	Gastrointestinal disorders/ Ascites/ ASCITES	16AUG2012 /35	13OCT2012 /67	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0002/55 /M/A2/Y	Psychiatric disorders/ Insomnia/ INSOMNIA	16AUG2012 /35	13OCT2012 /67	I	1	0	1	5	1
	General disorders and administration site conditions/ Asthenia/ WEAKNESS	16AUG2012 /35	13OCT2012 /67	C	1	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	31JUL2012 /19	13OCT2012 /67	C	1	0	1	5	1
	Injury, poisoning and procedural complications/ Skin abrasion/ RIGHT FOOT ABRASIONS	16JUL2012 /4	16AUG2012 /9	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0003/61 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	15MAY2013 /98	29APR2014 /377	I	1	1	1	5	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	14MAR2013 /36	29APR2014 /377	I	1	1	1	5	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	16FEB2013 /10	29APR2014 /377	I	1	0	1	5	1
310-0008/49 /M/A2/Y	Gastrointestinal disorders/ Gastric ulcer/ GASTRIC ULCERS	05JUL2013 /16	13AUG2013 /55	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0008/49 /M/A2/Y	Gastrointestinal disorders/ Gastritis/ ERYTHEMATOUS GASTRITIS	05JUL2013 /16	13AUG2013 /55	C	1	0	1	5	1
	Gastrointestinal disorders/ Varices oesophageal/ FAINT ESOPHAGEAL VARICES	05JUL2013 /16	13AUG2013 /55	C	1	0	1	5	1
	Nervous system disorders/ Dizziness/ DIZZINESS	05JUL2013 /16	13AUG2013 /55	I	1	0	1	5	1
	Gastrointestinal disorders/ Melaena/ TARRY STOOL	01JUL2013 /12	08JUL2013 /19	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0008/49 /M/A2/Y	General disorders and administration site conditions/ Malaise/ MALAISE	27JUN2013 /8	13AUG2013 /55	C	1	0	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	28JUN2013 /9	07JUL2013 /18	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	27JUN2013 /8	13AUG2013 /55	C	4	2	2	5 [PD]	3
	Gastrointestinal disorders/ Nausea/ NAUSEA	27JUN2013 /8	13AUG2013 /55	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0008/49 /M/A2/Y	Gastrointestinal disorders/ Vomiting/ VOMITING	27JUN2013 /8	13AUG2013 /55	I	1	1	1	5	2
	Investigations/ C-reactive protein increased/ CRP INCREASE	26JUN2013 /7	13AUG2013 /55	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	26JUN2013 /7	13AUG2013 /55	C	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMEN DISTENTION	26JUN2013 /7	08JUL2013 /19	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0008/49 /M/A2/Y	Skin and subcutaneous tissue disorders/ Rash/ PALMOPLANTAR ERUPTION	23JUN2013 /4	10JUL2013 /21	C	1	1	1	3	1
	Skin and subcutaneous tissue disorders/ Rash erythematous/ ITCHING ERYTHEMATOUS PLAQUES ON RIGHT ARM	23JUN2013 /4	10JUL2013 /21	C	1	1	3 /26JUN2013 /Unknown	3	2
310-0012/73 /M/A2/N	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	22APR2014 /166	Unknown/NA	I	6	0	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	01APR2014 /145	21APR2014 /11	C	2	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0012/73 /M/A2/N	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	29JAN2014 /83	03FEB2014 /-66	C	1	1	1	5	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	02DEC2013 /25	02DEC2013 /-129	C	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	23JAN2014 /77	27JAN2014 /-73	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	26NOV2013 /19	10DEC2013 /-121	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0012/73 /M/A2/N	Injury, poisoning and procedural complications/ Limb injury/ RIGHT FOOT WOUND	25MAR2014 /138	03APR2014 /-7	C	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEG PAIN	24FEB2014 /109	14MAR2014 /-27	C	1	0	1	5	2
	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN ITCHY	19DEC2013 /42	09JAN2014 /-91	C	1	1	1	5	2
	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	16DEC2013 /39	25DEC2013 /-106	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0012/73 /M/A2/N	Vascular disorders/ Hypertension/ HYPERTENSION	26NOV2013 /19	Unknown/NA	C	6	1	1	5	2
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	26NOV2013 /19	10DEC2013 /-121	C	1	0	1	5	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	26NOV2013 /19	31MAR2014 /-10	C	1	0	1	5	1
	Infections and infestations/ Localised infection/ LEFT FOOT 3RD TOE WOUND INFECTION	27NOV2013 /20	03DEC2013 /-128	C	1	3	1	5[Fender-Be nder]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0012/73 /M/A2/N	Injury, poisoning and procedural complications/ Limb injury/ FOOT INJURY	23NOV2013 /16	10DEC2013 /-121	C	1	3	1	5	2
	Injury, poisoning and procedural complications/ Head injury/ HEAD INJURY	23NOV2013 /16	05DEC2013 /-126	C	1	3	1	5	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	08NOV2013 /1	02DEC2013 /-129	C	1	0	1	5	2
310-0013/54 /M/A2/N	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	17DEC2014 /105	07JAN2015 /56	C	1	0	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0013/54 /M/A2/N	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	01DEC2014 /89	29APR2015 /168	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	22OCT2014 /49	05NOV2014 /-7	C	1	1	1	4	4
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	13OCT2014 /40	21OCT2014 /-22	C	1	0	1	4	1
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	13OCT2014 /40	14OCT2014 /-29	I	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0013/54 /M/A2/N	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	08OCT2014 /35	12OCT2014 /-31	I	1	0	1	3	1
	Cardiac disorders/ Sinus tachycardia/ SINUS TACHYCARDIA	01OCT2014 /28	01OCT2014 /-42	C	1	0	1	5	2
	Gastrointestinal disorders/ Stomatitis/ MUCOSITIS ORAL	28SEP2014 /25	10OCT2014 /-33	C	1	0	1	5	1
311-0002/60 /M/A2/Y	Musculoskeletal and connective tissue disorders/ Arthralgia/ BILATERAL SHOULDER AND HAND JOINTS PAIN	19SEP2013 /36	25SEP2013 /-7	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
311-0002/60 /M/A2/Y	Gastrointestinal disorders/ Gastric ulcer/ GASTRIC ULCER	05SEP2013 /22	Unknown/NA	C	6	1	1	5	2
	Skin and subcutaneous tissue disorders/ Rash pruritic/ ITCHING SKIN RASH	11SEP2013 /28	23SEP2013 /-9	I	1	1	1	5	3
	Gastrointestinal disorders/ Duodenal ulcer/ DOUDENUM ULCER	05SEP2013 /22	Unknown/NA	C	6	1	1	5	2
	General disorders and administration site conditions/ Disease progression/ WORSENING OF HEPATIC CARCINOMA	16OCT2013 /63	29OCT2013 /27	C	1	2	1	5 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
311-0002/60 /M/A2/Y	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	02SEP2013 /19	Unknown/NA	C	6	1	1	5	2
	Infections and infestations/ Cellulitis/ BILETERAL LEG CELLULITIS	30AUG2013 /16	13SEP2013 /-19	C	1	1	3 /11SEP2013 /18SEP2013	5	3
311-0007/55 /M/A2/Y	Injury, poisoning and procedural complications/ Wound/ BILATERAL POST-BULLA FORMATION OPEN WOUND OVER FOREARMS	30DEC2013 /42	20FEB2014 /31	C	1	1	1	5	2
	Cardiac disorders/ Palpitations/ PALPITATION	09DEC2013 /21	24FEB2014 /35	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
401-0003/36 /M/A7/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to spleen/ SPLEEN METASTASIS	08SEP2013 /75	14SEP2013 /18	C	1	0	1	4 [PD]	2
	Vascular disorders/ Embolism/ THROMBOEMBOLIC EVENT	03SEP2013 /70	Unknown/NA	C	6	1	1	5	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	09AUG2013 /45	Unknown/NA	I	6	1	1	3	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	26JUL2013 /31	31JUL2013 /-27	I	3	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
401-0003/36 /M/A7/Y	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ PAIN AT RIGHT SHOULDER	25JUN2013 /0	12JUL2013 /-46	I	3	1	1	5	1
	Injury, poisoning and procedural complications/ Fracture/ FRACTURE	30JUL2013 /35	07AUG2013 /-20	C	1	1	1	5[Accident]	3
	Gastrointestinal disorders/ Abdominal pain lower/ PAIN AT LLQ	17AUG2013 /53	30AUG2013 /3	I	1	0	1	4	2
	Nervous system disorders/ Dizziness/ DIZZINESS	26JUL2013 /31	30JUL2013 /-28	I	1	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
401-0003/36 /M/A7/Y	Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	21JUL2013 /26	26JUL2013 /-32	I	1	1	1	4 [CD]	1
	Musculoskeletal and connective tissue disorders/ Flank pain/ PAIN AT LEFT FLANK	05JUL2013 /10	21JUL2013 /-37	I	1	1	1	4 [CD]	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	25JUN2013 /0	31JUL2013* /-27	I	2	1	1	4 [CM]	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	25JUN2013 /0	Unknown/NA	I	6	1	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
401-0003/36 /M/A7/Y	General disorders and administration site conditions/ Chest discomfort/ CHEST DISCOMFORT,NOT SPECIFIED	25JUN2013 /0	26JUN2013 /-62	I	1	0	1	5 [CD]	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	04AUG2013 /40	04AUG2013 /-23	I	1	0	1	4	1
401-0005/58 /M/A7/Y	Gastrointestinal disorders/ Constipation/ CONSTIPATION	14DEC2013 /59	Unknown/NA	I	5	1	1	5	1
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to bone/ BONE METASTASIS	24DEC2013 /69	24JAN2014 /44	C	1	1	1	5 [PD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
401-0005/58 /M/A7/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Cancer pain/ CANCER PAIN	28NOV2013 /43	Unknown/NA	I	6	1	1	5	2
	Renal and urinary disorders/ Dysuria/ DYSURIA	06DEC2013 /51	12DEC2013 /1	I	1	1	1	5	2
	Gastrointestinal disorders/ Abdominal discomfort/ ABDOMINAL DISCOMFORT	02DEC2013 /47	07DEC2013 /-4	I	1	0	1	5	1
	Nervous system disorders/ Paraesthesia/ PARESTHESIA	17NOV2013 /32	Unknown/NA	I	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
401-0005/58 /M/A7/Y	Gastrointestinal disorders/ Constipation/ CONSTIPATION	18NOV2013 /33	07DEC2013 /-4	I	1	1	1	5	1
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to bone/ BONE METASTASIS	15NOV2013 /30	28NOV2013 /-13	C	1	3	1	5[CD]	3
	Investigations/ Neutrophil count decreased/ NEUTROPHIL COUNT DECREASED	05NOV2013 /20	12NOV2013 /-29	C	1	1	3 /05NOV2013 /11NOV2013	4	3
	Renal and urinary disorders/ Dysuria/ DYSURIA	28OCT2013 /12	05NOV2013 /-36	I	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
401-0005/58 /M/A7/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	28OCT2013 /12	05NOV2013 /-36	I	1	0	1	4	1
402-0003/75 /M/A7/Y	Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RINORRHEA	12OCT2013 /165	Unknown/NA	C	6	1	1	5	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	11OCT2013 /164	Unknown/NA	C	6	1	1	3	2
	Musculoskeletal and connective tissue disorders/ Flank pain/ PAIN(RIGHT FLANK, BACK)	14OCT2013 /167	Unknown/NA	C	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0003/75 /M/A7/Y	Renal and urinary disorders/ Haematuria/ HEMATURIA	15OCT2013 /168	Unknown/NA	C	6	0	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	09OCT2013 /162	Unknown/NA	C	6	2	1	5	2
	Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	12SEP2013 /135	07OCT2013 /-1	C	1	1	1	4	2
	Renal and urinary disorders/ Haematuria/ HEMATURIA	10SEP2013 /133	29SEP2013 /-9	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0003/75 /M/A7/Y	Skin and subcutaneous tissue disorders/ Rash/ RASH(SCALP)	26JUN2013 /57	14AUG2013 /-55	C	1	0	1	2	1
402-0006/71 /M/A7/Y	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	13MAY2013 /11	14MAY2013 /-69	C	1	3	3 /09MAY2013 /21MAY2013	5[Cancer Related]	2
	General disorders and administration site conditions/ Chills/ CHILLING	05MAY2013 /3	05MAY2013 /-78	C	1	0	1	3	1
402-0008/43 /M/A7/N	General disorders and administration site conditions/ Pyrexia/ FEVER	18JUN2013 /28	24JUN2013 /27	I	1	1	1	5[PD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0008/43 /M/A7/N	General disorders and administration site conditions/ Disease progression/ DISEASE PROGRESSION	03JUN2013 /13	10JUN2013 /13	C	1	0	2	5 [PD]	3
	General disorders and administration site conditions/ Fatigue/ FATIGUE	21MAY2013 /0	Unknown/NA	C	6	0	1	2	1
402-0009/70 /M/A7/Y	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	18JUL2013 /63	18JUL2013 /14	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	14JUL2013 /59	15JUL2013 /11	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0009/70 /M/A7/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	15JUL2013 /60	15JUL2013 /11	C	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	12JUL2013 /57	Unknown/NA	C	6	1	1	5	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	21JUN2013 /36	11JUL2013 /7	C	1	0	1	5	1
	Psychiatric disorders/ Confusional state/ CONFUSION	01JUN2013 /16	11JUN2013 /-23	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0009/70 /M/A7/Y	Nervous system disorders/ Dizziness/ DIZZINESS	24MAY2013 /8	Unknown/NA	C	6	0	1	2	1
	Gastrointestinal disorders/ Dyspepsia/ DYSPEPSIA	24MAY2013 /8	Unknown/NA	C	6	1	1	2	1
402-0011/64 /M/A7/Y	Renal and urinary disorders/ Urinary retention/ URINARY RETENSION	01AUG2013 /70	Unknown/NA	C	6	0	1	5	1
	General disorders and administration site conditions/ Non-cardiac chest pain/ NON-CARDIAC CHEST PAIN,RIGHT	14JUN2013 /22	Unknown/NA	I	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0011/64 /M/A7/Y	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	14JUN2013 /22	Unknown/NA	I	6	0	1	5	1
402-0017/50 /M/A7/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ PROGRESSION OF NEOPLASTIC DISEASE	08AUG2013 /52	09AUG2013 /8	C	4	3	2	5 [PD]	5
	General disorders and administration site conditions/ Asthenia/ GENERAL WEAKNESS	26JUL2013 /39	Unknown/NA	C	6	0	1	3	2
	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	25JUL2013 /38	Unknown/NA	C	6	0	1	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0017/50 /M/A7/Y	Vascular disorders/ Hypertension/ HIGH BLOOD PRESSURE	18JUL2013 /31	Unknown/NA	C	6	1	1	3	1
	General disorders and administration site conditions/ Asthenia/ GENERAL WEAKNESS	02JUL2013 /15	25JUL2013 /-7	C	1	0	1	3	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	20JUN2013 /3	Unknown/NA	C	6	0	1	5	1
402-0018/48 /M/A7/Y	Musculoskeletal and connective tissue disorders/ Bone pain/ PAIN(LT.ILIAC BONE)	30AUG2013 /67	Unknown/NA	C	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0018/48 /M/A7/Y	Gastrointestinal disorders/ Vomiting/ VOMITING	26AUG2013 /63	30AUG2013 /-10	C	1	1	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	26AUG2013 /63	30AUG2013 /-10	C	1	1	1	3	2
402-0019/54 /M/A7/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA (INTERMITTENT)	18SEP2013 /79	Unknown/NA	C	6	0	1	2	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	13SEP2013 /74	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0019/54 /M/A7/N	Investigations/ Aspartate aminotransferase increased/ INCREASED AST	16SEP2013 /77	Unknown/NA	C	6	0	3 /23SEP2013 /Unknown	3	3
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	17JUL2013 /16	20JUL2013 /-51	C	1	0	1	1	1
	Skin and subcutaneous tissue disorders/ Palmar-plantar erythrodysaesthesia syndrome/ HANDFOOT SYNDROME	09JUL2013 /8	20AUG2013 /-20	C	1	0	1	1	1
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH (BOTH ARM)	09JUL2013 /8	20AUG2013 /-20	C	1	0	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0019/54 /M/A7/N	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH(WHOLE BODY)	02JUL2013 /1	03JUL2013 /-68	C	1	0	1	2	1
402-0021/64 /M/A7/N	Ear and labyrinth disorders/ Tinnitus/ TINNITUS	18DEC2013 /127	Unknown/NA	I	6	0	1	4	1
402-0024/57 /M/A7/Y	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYPSPNEA	20NOV2013 /85	24DEC2013 /49	C	4	3	1	5[PD]	3
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYPSPNEA	01NOV2013 /66	19NOV2013 /14	C	3	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0024/57 /M/A7/Y	Investigations/ Alanine aminotransferase increased/ INCREASED ALT	08OCT2013 /42	Unknown/NA	C	6	0	3 /08OCT2013 /29OCT2013	5	3
	Investigations/ Alanine aminotransferase increased/ INCREASED ALT	17SEP2013 /21	30SEP2013 /-36	C	1	0	3 /17SEP2013 /29OCT2013	5	3
	Investigations/ Aspartate aminotransferase increased/ INCREASED AST	17SEP2013 /21	Unknown/NA	C	6	0	3 /17SEP2013 /29OCT2013	5	3
402-0025/58 /M/A7/Y	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	01JAN2014 /98	Unknown/NA	C	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0025/58 /M/A7/Y	Nervous system disorders/ Headache/ HEADACHE	18OCT2013 /23	19OCT2013 /-54	C	1	0	1	3	1
402-0027/52 /M/A7/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ PROGRESSION OF NEOPLASTIC DISEASE	28NOV2013 /55	28NOV2013 /23	C	4	2	1	5 [PD]	5
	General disorders and administration site conditions/ Oedema peripheral/ LEG EDEMA	06NOV2013 /33	Unknown/NA	C	6	0	1	5	1
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	05NOV2013 /32	13NOV2013 /8	C	1	1	1	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0027/52 /M/A7/Y	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	26OCT2013 /22	Unknown/NA	C	6	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	29OCT2013 /25	Unknown/NA	C	6	1	1	3	1
	Reproductive system and breast disorders/ Testicular oedema/ EDEMA OF TESTIS	21OCT2013 /17	Unknown/NA	C	6	1	1	5	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	13OCT2013 /9	Unknown/NA	C	6	1	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0027/52 /M/A7/Y	Gastrointestinal disorders/ Dyspepsia/ DYSPEPSIA	13OCT2013 /9	Unknown/NA	C	6	1	1	2	1
	Skin and subcutaneous tissue disorders/ Pruritus generalised/ ITCHING (WHOLE BODY)	05OCT2013 /1	11OCT2013 /-25	C	1	0	1	2	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	13OCT2013 /9	20OCT2013 /-16	C	1	3	1	2	2
402-0028/60 /M/A7/Y	Reproductive system and breast disorders/ Pelvic pain/ PELVIC PAIN	23DEC2013 /80	Unknown/NA	C	6	1	1	5[Hcc]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0028/60 /M/A7/Y	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ PAIN BOTH SHOULDER	23DEC2013 /80	Unknown/NA	C	6	1	1	5[Hcc]	3
	Gastrointestinal disorders/ Nausea/ NAUSEA	01DEC2013 /58	09DEC2013 /-3	C	1	1	1	5	1
	Nervous system disorders/ Hypoaesthesia/ NUMBNESS	22OCT2013 /18	Unknown/NA	C	6	1	1	5	2
	Gastrointestinal disorders/ Abdominal pain lower/ PAIN BOTH ILIAC	05NOV2013 /32	23NOV2013 /-19	I	1	1	1	5[Hcc]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0028/60 /M/A7/Y	Investigations/ Weight decreased/ WEIGHT LOSS	12DEC2013 /69	Unknown/NA	C	6	0	1	3	1
	Ear and labyrinth disorders/ Otorrhoea/ OTORRHEA	26NOV2013 /53	Unknown/NA	C	6	1	1	3	1
	Ear and labyrinth disorders/ Tinnitus/ TINNITUS	26NOV2013 /53	Unknown/NA	C	6	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT THIGH PAIN	22OCT2013 /18	Unknown/NA	C	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0028/60 /M/A7/Y	Investigations/ Blood cholesterol increased/ CHOLESTEROL HIGH	05NOV2013 /32	Unknown/NA	C	6	1	1	3	2
402-0031/65 /M/A7/Y	Metabolism and nutrition disorders/ Hypophosphataemia/ HYPOPHOSPHATEMIA	26NOV2013 /14	Unknown/NA	C	6	1	1	3	3
	Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	21NOV2013 /9	27NOV2013 /-63	C	1	1	1	2	2
402-0033/63 /F/A7/N	Skin and subcutaneous tissue disorders/ Swelling face/ RIGHT BUCCAL SWELLING	26JAN2014 /51	28JAN2014 /8	C	1	1	3 /27JAN2014 /Unknown	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0033/63 /F/A7/N	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	14JAN2014 /39	Unknown/NA	I	6	0	1	3	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	23DEC2013 /17	Unknown/NA	C	6	0	1	2	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	17DEC2013 /11	Unknown/NA	C	6	1	1	2	1
402-0035/44 /M/A7/Y	Injury, poisoning and procedural complications/ Injury/ INJURY TO FLANK	06JAN2014 /13	Unknown/NA	C	6	2	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0035/44 /M/A7/Y	Injury, poisoning and procedural complications/ Joint injury/ INJURY TO HIP	06JAN2014 /13	Unknown/NA	C	6	2	1	5	2
403-0001/55 /M/A7/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	05JUL2013 /43	31JUL2013* /35	I	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Flank pain/ PAIN(RT.FLANK)	20JUL2013 /58	Unknown/NA	I	6	1	1	5	2
	General disorders and administration site conditions/ Non-cardiac chest pain/ NON CARDIAC CHEST PAIN	01JUN2013* /9	Unknown/NA	I	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0001/55 /M/A7/Y	Musculoskeletal and connective tissue disorders/ Back pain/ PAIN (BACK)	01JUN2013* /9	Unknown/NA	I	6	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Laryngeal haemorrhage/ LARYNGEAL HEMORRHAGE	17JUN2013 /25	30JUN2013* /4	I	1	0	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	05JUL2013 /43	08JUL2013 /12	I	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	23MAY2013* /0	Unknown/NA	C	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0001/55 /M/A7/Y	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	01JUN2013* /9	Unknown/NA	I	6	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	24MAY2013 /1	15JUL2013 /19	C	1	0	1	3	1
403-0002/52 /M/A7/N	Investigations/ Weight decreased/ WEIGHT LOSS	31JUL2013 /49	Unknown/NA	C	6	0	1	3	2
	Gastrointestinal disorders/ Dyspepsia/ HEARTBURN	01SEP2013* /81	Unknown/NA	I	6	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0002/52 /M/A7/N	Psychiatric disorders/ Insomnia/ INSOMNIA	01SEP2013* /81	Unknown/NA	C	6	1	1	5	2
	Vascular disorders/ Embolism/ THROMBOEMBOLIC EVENT	23AUG2013 /72	Unknown/NA	C	6	1	1	5	3
	Skin and subcutaneous tissue disorders/ Rash/ RASH	25AUG2013 /74	Unknown/NA	C	6	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Flank pain/ FLANK PAIN (RT)	01AUG2013* /50	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0002/52 /M/A7/N	General disorders and administration site conditions/ Non-cardiac chest pain/ NON-CARDIAC CHEST PAIN(RT)	01AUG2013* /50	Unknown/NA	I	6	1	1	5	1
	General disorders and administration site conditions/ Asthenia/ GENERAL WEAKNESS	01AUG2013* /50	Unknown/NA	C	6	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	01AUG2013* /50	Unknown/NA	I	6	0	1	5	1
	Nervous system disorders/ Dizziness/ DIZZINESS	13AUG2013 /62	11SEP2013 /29	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0002/52 /M/A7/N	General disorders and administration site conditions/ Asthenia/ ASTHENIA	01JUL2013* /19	Unknown/NA	C	6	0	1	2	1
	Reproductive system and breast disorders/ Pelvic pain/ PAIN (PELVIS)	31JUL2013 /49	31JUL2013 /-13	C	1	0	1	4	2
	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	17JUL2013 /35	17JUL2013 /-27	C	1	0	1	5	1
	Gastrointestinal disorders/ Toothache/ TOOTHACHE	17JUL2013 /35	17JUL2013 /-27	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0002/52 /M/A7/N	Reproductive system and breast disorders/ Pelvic pain/ PAIN (PELVIS)	10JUL2013 /28	10JUL2013 /-34	C	1	0	1	2	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	10JUL2013 /28	10JUL2013 /-34	C	1	0	1	5	1
	Gastrointestinal disorders/ Dyspepsia/ DYSPEPSIA	10JUL2013 /28	10JUL2013 /-34	C	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA (WHOLE BODY)	10JUL2013 /28	10JUL2013 /-34	I	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0002/52 /M/A7/N	General disorders and administration site conditions/ Chills/ CHILLS	28JUN2013 /16	28JUN2013 /-46	C	1	0	1	2	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	12JUN2013* /0	Unknown/NA	C	6	0	1	2	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	12JUN2013* /0	Unknown/NA	C	6	0	1	2	1
	General disorders and administration site conditions/ Injection site oedema/ INJECTION SITE EDEMA	26JUN2013 /14	30JUN2013 /-44	C	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0002/52 /M/A7/N	General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	26JUN2013 /14	30JUN2013 /-44	C	1	0	1	2	1
	Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIA	18JUN2013 /6	Unknown/NA	C	6	1	1	2	1
	General disorders and administration site conditions/ Injection site reaction/ INJECTION SITE REACTION	18JUN2013 /6	30JUN2013 /-44	C	1	1	1	2	1
	Immune system disorders/ Hypersensitivity/ ALLERGIC REACTION	13AUG2013 /62	13AUG2013 /0	C	1	1	1	2	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0005/50 /F/A7/Y	Nervous system disorders/ Headache/ HEADACHE	22AUG2013 /36	28AUG2013 /30	I	1	1	1	5	2
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to central nervous system/ BRAIN METASTASIS	02AUG2013 /16	08AUG2013 /10	I	1	3	2	5 [PD]	3
	Nervous system disorders/ Headache/ HEADACHE	24JUL2013 /7	30JUL2013 /1	C	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ HEMOPTYSIS	24JUL2013 /7	26JUL2013 /-3	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0005/50 /F/A7/Y	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	24JUL2013 /7	Unknown/NA	C	6	1	1	5	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	26JUL2013 /9	30JUL2013 /1	I	1	0	1	5	2
	Infections and infestations/ Nasopharyngitis/ COMMON COLD	24JUL2013 /7	30JUL2013 /1	C	1	0	1	5	2
	General disorders and administration site conditions/ Non-cardiac chest pain/ CHEST PAIN (NON-CARDIAC)	17JUL2013 /0	20JUL2013 /-9	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0005/50 /F/A7/Y	Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	17JUL2013 /0	19JUL2013 /-10	C	1	0	1	2	1
	Skin and subcutaneous tissue disorders/ Pruritus generalised/ PRUTIRUS (WHOLE BODY)	21JUL2013 /4	21JUL2013 /-8	C	1	0	1	2	1
403-0006/66 /M/A7/Y	Gastrointestinal disorders/ Toothache/ TOOTHACHE	01SEP2013* /32	20OCT2013 /3	I	1	0	1	5	2
	Gastrointestinal disorders/ Stomatitis/ MUCOSITIS ORAL	10OCT2013 /71	Unknown/NA	C	6	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0006/66 /M/A7/Y	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	01OCT2013 /62	13OCT2013 /-4	C	1	0	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	01OCT2013 /62	08OCT2013 /-9	C	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORETHROAT	01OCT2013 /62	13OCT2013 /-4	C	1	0	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	24SEP2013 /55	30SEP2013 /-17	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0006/66 /M/A7/Y	Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	24SEP2013 /55	30SEP2013 /-17	C	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	24SEP2013 /55	30SEP2013 /-17	C	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA	02SEP2013 /33	03SEP2013 /-44	I	1	0	1	5	2
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	23AUG2013 /23	28AUG2013 /-50	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0006/66 /M/A7/Y	Skin and subcutaneous tissue disorders/ Dermatitis acneiform/ RASH ACNEFORM	23AUG2013 /23	28AUG2013 /-50	C	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	01AUG2013* /1	02SEP2013 /-45	C	1	0	1	3	1
	Gastrointestinal disorders/ Stomatitis/ MUCOSITIS ORAL	19AUG2013 /19	09OCT2013 /-8	C	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	07AUG2013 /7	02SEP2013 /-45	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0006/66 /M/A7/Y	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	04AUG2013 /4	04AUG2013 /-74	I	1	0	1	5	1
	Gastrointestinal disorders/ Periodontal disease/ PERIODONTAL DISEASE	02AUG2013 /2	Unknown/NA	I	6	0	1	3	1
403-0007/65 /M/MIX/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	21AUG2013* /0	30SEP2013* /-38	I	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ WORSENING OF ARTHRALGIA	01SEP2013* /11	Unknown/NA	C	6	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0007/65 /M/MIX/Y	Respiratory, thoracic and mediastinal disorders/ Laryngeal haemorrhage/ LARYNGEAL HEMORRHAGE	30SEP2013 /40	04OCT2013 /-34	I	1	1	3 /01OCT2013 /08OCT2013	5[CD]	2
	Skin and subcutaneous tissue disorders/ Rash/ RASH	05SEP2013 /15	09SEP2013 /-59	C	1	0	1	2	1
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	05SEP2013 /15	09SEP2013 /-59	C	1	0	1	2	1
	General disorders and administration site conditions/ Injection site rash/ RASH(INJECTION SITE)	21AUG2013 /0	21AUG2013 /-78	C	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
404-0001/71 /M/A7/Y	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	11SEP2013 /51	11SEP2013 /30	I	4	1	1	5 [PD]	5
	Psychiatric disorders/ Anxiety/ ANXIETY	31AUG2013 /40	31AUG2013 /19	I	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Hiccups/ HICCUP	23AUG2013 /32	01SEP2013 /20	I	1	1	1	5	2
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	07AUG2013 /16	Unknown/NA	C	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
404-0001/71 /M/A7/Y	General disorders and administration site conditions/ Oedema peripheral/ FOUR EXTREMITIES EDEMA	09SEP2013 /49	Unknown/NA	C	6	0	1	5	3
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	09SEP2013 /49	Unknown/NA	C	6	3	1	5	3
	Nervous system disorders/ Somnolence/ SOMNOLENCE	05SEP2013 /45	Unknown/NA	C	6	2	1	5	3
	General disorders and administration site conditions/ Pain/ GENERALIZED PAIN	04SEP2013 /44	Unknown/NA	C	6	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
404-0001/71 /M/A7/Y	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	25AUG2013 /34	08SEP2013 /27	I	3	3	1	5	2
	Infections and infestations/ Candida infection/ CANDIDA INFECTION	19AUG2013 /28	Unknown/NA	C	6	1	1	5	3
	Renal and urinary disorders/ Hydronephrosis/ HYDRONEPHROSIS	13AUG2013 /22	Unknown/NA	C	6	2	1	5	3
	Blood and lymphatic system disorders/ Leukocytosis/ LEUKOCYTOSIS	10AUG2013 /19	19AUG2013 /7	C	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
404-0001/71 /M/A7/Y	General disorders and administration site conditions/ Oedema peripheral/ BOTH LOWER LEG EDEMA	07AUG2013 /16	Unknown/NA	C	6	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Musculoskeletal discomfort/ BACK DISCOMFORT	06AUG2013 /15	Unknown/NA	C	6	1	1	5	1
	Hepatobiliary disorders/ Hepatic failure/ HEPATIC FAILURE	05AUG2013 /14	Unknown/NA	C	6	1	1	5	3
	Respiratory, thoracic and mediastinal disorders/ Atelectasis/ ATELECTASIS	05AUG2013 /14	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
404-0001/71 /M/A7/Y	Psychiatric disorders/ Confusional state/ CONFUSION	05AUG2013 /14	08AUG2013 /-4	I	1	1	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	01AUG2013 /10	02AUG2013 /-10	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	30JUL2013 /8	Unknown/NA	C	6	1	1	3	3
	Gastrointestinal disorders/ Nausea/ NAUSEA	30JUL2013 /8	31JUL2013 /-12	C	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
404-0001/71 /M/A7/Y	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	27JUL2013 /5	29JUL2013 /-14	C	3	1	1	3	2
	Ear and labyrinth disorders/ Tinnitus/ TINNITUS	25JUL2013 /3	09AUG2013 /-3	I	1	0	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	25JUL2013 /3	27JUL2013 /-16	I	1	1	1	3	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	22JUL2013 /0	10SEP2013 /29	I	1	1	1	5 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
404-0002/56 /F/A7/Y	General disorders and administration site conditions/ Disease progression/ PROGRESSION DISEASE OF HCC	12SEP2013 /21	Unknown/NA	I	5	1	2	4 [PD]	3
	Skin and subcutaneous tissue disorders/ Alopecia/ ALOPECIA	29SEP2013 /38	Unknown/NA	C	6	0	1	5	2
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIGHT SCAPULAR PAIN	08SEP2013 /17	Unknown/NA	C	6	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGHING	08SEP2013 /17	25DEC2013 /111	I	3	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
404-0002/56 /F/A7/Y	General disorders and administration site conditions/ Injection site erythema/ SKIN REDNESS (INJECTION SITE)	04SEP2013 /13	11SEP2013 /6	C	1	0	1	1	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	02SEP2013 /11	Unknown/NA	I	6	0	1	5	1
405-0002/46 /M/A7/Y	Gastrointestinal disorders/ Oesophageal varices haemorrhage/ ESOPHAGEAL VARIX BLEEDING	30APR2013 /14	12MAY2013 /12	I	4	3	2	4 [CD]	3
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	26APR2013 /10	Unknown/NA	C	6	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0002/46 /M/A7/Y	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	20APR2013 /4	26APR2013 /-4	C	1	0	1	4	1
	Gastrointestinal disorders/ Portal hypertensive gastropathy/ PORTAL HYPERTENSIVE GASTROPATHY	20APR2013 /4	23APR2013 /-7	I	1	1	1	4 [CD]	3
	General disorders and administration site conditions/ Pyrexia/ FEVER	16APR2013 /0	17APR2013 /-13	C	1	1	1	4	1
405-0004/38 /M/A7/Y	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	30JUL2013 /97	Unknown/NA	I	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0004/38 /M/A7/Y	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT PAIN	30JUL2013 /97	Unknown/NA	I	6	0	1	5	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	30JUL2013 /97	Unknown/NA	I	6	0	1	5	1
	Gastrointestinal disorders/ Dyspepsia/ DYSPEPSIA	30JUL2013 /97	Unknown/NA	I	6	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	20JUN2013 /57	Unknown/NA	I	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0004/38 /M/A7/Y	Nervous system disorders/ Headache/ HEADACHE (OCCIPITAL)	08MAY2013 /14	09MAY2013 /-55	I	1	0	1	4	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ BOTH KNEE PAIN	30APR2013 /6	Unknown/NA	I	6	0	1	4	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIFHT BUTTOCK TENDERNESS	29APR2013 /5	23MAY2013 /-41	I	1	0	1	3	1
405-0006/62 /M/A7/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to central nervous system/ BRAIN METASTASIS IN THE LT. FRONTAL LOB	31MAY2013 /32	10JUN2013 /12	C	4	1	2	4 [PD]	5

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0006/62 /M/A7/Y	Nervous system disorders/ Brain stem infarction/ ACUTE INFECTARCTION IN THE PONS AND BOTH PICA TERRITORY	31MAY2013 /32	10JUN2013 /12	C	4	1	2	4 [PD]	5
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	23MAY2013 /24	Unknown/NA	I	6	1	1	4	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	29APR2013 /0	16MAY2013 /-13	I	1	0	1	4	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	10MAY2013 /11	Unknown/NA	C	6	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0006/62 /M/A7/Y	Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	08MAY2013 /9	Unknown/NA	I	6	1	1	4	1
	Gastrointestinal disorders/ Dyspepsia/ DYSPEPSIA	30APR2013 /1	Unknown/NA	I	6	1	1	4	1
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING SENSE ON RIGHT UPPER BACK	30APR2013 /1	Unknown/NA	I	6	0	1	4	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMEN PAIN	30APR2013 /1	Unknown/NA	I	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0007/53 /M/A7/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	24SEP2013 /140	Unknown/NA	C	6	1	1	4	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	05JUL2013 /59	Unknown/NA	C	6	0	1	4	1
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING SENSE AT BOTH BUTTOCK	08JUN2013 /32	15JUN2013 /-103	I	1	1	1	3	1
405-0009/50 /M/A7/N	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING SENSE	07JUL2013 /54	19AUG2013 /34	I	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0009/50 /M/A7/N	Skin and subcutaneous tissue disorders/ Rash/ SKIN ERUPTION	07JUL2013 /54	19AUG2013 /34	I	1	1	1	4	2
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING SENSE	29MAY2013 /15	30JUN2013 /-16	I	1	1	1	4	2
	Gastrointestinal disorders/ Ascites/ ASCITES	24JUL2013 /71	29JUL2013 /13	C	1	2	2	4 [CD]	3
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	13JUL2013 /60	19AUG2013 /34	I	1	1	1	4 [Due To Rule Out Ascites]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0009/50 /M/A7/N	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	03JUL2013 /50	19AUG2013 /34	C	1	0	1	4	1
	General disorders and administration site conditions/ Non-cardiac chest pain/ NON CARDIAC CHEST PAIN	29MAY2013 /15	19AUG2013 /34	I	1	0	1	4	1
	Skin and subcutaneous tissue disorders/ Rash/ SKIN ERUPTION	29MAY2013 /15	30JUN2013 /-16	I	1	1	1	4	2
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	29MAY2013 /15	19AUG2013 /34	I	1	1	1	4[Because Of Lung Mass]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0009/50 /M/A7/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	23MAY2013 /9	29MAY2013 /-48	I	1	1	1	4	1
405-0010/39 /M/A7/Y	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	30JUL2013 /68	Unknown/NA	C	6	0	1	4	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	26JUL2013 /64	Unknown/NA	I	6	1	1	4	3
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	26JUL2013 /64	Unknown/NA	I	6	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0010/39 /M/A7/Y	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING SENSE	23MAY2013 /0	23MAY2013 /-75	C	1	1	1	2	2
	Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA	23MAY2013 /0	23MAY2013 /-75	C	1	1	1	2	2
405-0011/63 /M/A7/Y	Metabolism and nutrition disorders/ Hypophosphataemia/ HYPOPHOSPHATEMIA	21OCT2013 /161	Unknown/NA	C	6	1	1	4	2
	Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT KNEE PAIN	07OCT2013 /147	Unknown/NA	I	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0011/63 /M/A7/Y	General disorders and administration site conditions/ Fatigue/ FATIGUE	30SEP2013 /140	Unknown/NA	I	6	0	1	3	1
	Infections and infestations/ Oral herpes/ HERPES LABIALIS	28SEP2013 /138	06OCT2013 /-15	C	1	1	1	4	2
	Metabolism and nutrition disorders/ Hypocalcaemia/ HYPOCALCEMIA	30SEP2013 /140	Unknown/NA	C	6	1	1	4	1
	Metabolism and nutrition disorders/ Hypophosphataemia/ HYPOPHOSPHATEMIA	09SEP2013 /119	15SEP2013 /-36	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0011/63 /M/A7/Y	Nervous system disorders/ Somnolence/ SLEEP TENDENCY	13MAY2013 /0	12AUG2013 /-70	I	1	0	1	4	1
405-0013/45 /M/A7/N	Gastrointestinal disorders/ Haematemesis/ OCCASIONAL HEMATEMESIS	10SEP2013 /113	Unknown/NA	I	6	0	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	03SEP2013 /106	09SEP2013 /21	I	1	1	1	4	3
	Musculoskeletal and connective tissue disorders/ Muscle spasms/ LEFT LEG CLAMPING SENSE	05SEP2013 /108	Unknown/NA	C	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0013/45 /M/A7/N	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	02SEP2013 /105	Unknown/NA	I	6	0	2	4	3
	Nervous system disorders/ Dizziness/ DIZZINESS	19AUG2013 /91	Unknown/NA	I	6	0	1	4	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	05AUG2013 /77	11AUG2013 /-8	C	1	0	1	4	2
	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN ITCHING	20MAY2013 /0	15JUL2013 /-35	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0013/45 /M/A7/N	Nervous system disorders/ Headache/ HEADACHE	20MAY2013 /0	15JUL2013 /-35	I	1	0	1	4	1
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	07JUL2013 /48	Unknown/NA	I	6	0	1	4	1
	Immune system disorders/ Food allergy/ FOOD ALLERGY	14JUN2013 /25	17JUN2013 /-63	I	1	0	1	4	1
	Gastrointestinal disorders/ Dyspepsia/ DYSPEPSIA	06JUN2013 /17	Unknown/NA	I	6	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0013/45 /M/A7/N	Gastrointestinal disorders/ Ascites/ ASCITES	20JUN2013 /31	Unknown/NA	I	6	1	1	4	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	20JUN2013 /31	Unknown/NA	I	6	0	1	4	1
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	24JUN2013 /35	Unknown/NA	C	6	1	3 /24JUN2013 /01JUL2013	4	3
	Psychiatric disorders/ Insomnia/ INSOMNIA	22MAY2013 /2	30JUN2013 /-50	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0013/45 /M/A7/N	Immune system disorders/ Seasonal allergy/ WORSENING SEASONAL ALLERGIC RHINITIS	21MAY2013 /1	30JUN2013 /-50	I	1	1	1	5	1
	Infections and infestations/ Fungal infection/ FUNGAL INFECTION	04JUN2013 /15	30JUN2013 /-50	C	1	1	1	4	2
405-0014/35 /M/A7/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ PROGRESSION OF NEOPLASTIC DISEASE-LIVER	19JUL2013 /49	19JUL2013 /30	C	4	0	2	5 [PD]	5
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	27JUN2013 /27	19JUL2013 /30	C	1	0	1	4 [PD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0014/35 /M/A7/Y	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT PAIN	13JUN2013 /13	22JUN2013 /3	I	1	0	1	4[Cancer Pain]	1
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN ELEVATION	26JUN2013 /26	19JUL2013 /30	C	1	0	3 /26JUN2013 /02JUL2013	4	3
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	21JUN2013 /21	19JUL2013 /30	I	1	0	1	4	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	23JUN2013 /23	19JUL2013 /30	I	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0014/35 /M/A7/Y	Investigations/ Urine output decreased/ URINE OUTPUT DECREASED	23JUN2013 /23	27JUN2013 /8	I	1	0	1	4	1
	Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA	31MAY2013 /0	01JUN2013 /-18	I	1	0	1	3	1
405-0016/41 /M/A7/Y	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	13JUN2013 /17	14JUL2013 /34	I	1	1	1	4 [PD]	2
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ PROGRESSION OF NEOPLASTIC DISEASE-LIVER	05JUL2013 /39	14JUL2013 /34	C	4	1	1	5 [PD]	5

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0016/41 /M/A7/Y	Investigations/ Blood bilirubin increased/ BILIRUBIN ELEVATION	24JUN2013 /28	14JUL2013 /34	C	1	1	2	5 [PD]	3
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANPERASE ELEVATION	17JUN2013 /21	14JUL2013 /34	C	1	1	1	4 [PD]	3
	Gastrointestinal disorders/ Vomiting/ VOMITING	13JUN2013 /17	14JUL2013 /34	I	1	1	1	4[Related To Abnormal Liver Function]	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	13JUN2013 /17	14JUL2013 /34	I	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0016/41 /M/A7/Y	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	28MAY2013 /1	13JUN2013 /3	I	1	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ GENERAL MYALGIA	29MAY2013 /2	14JUL2013 /34	I	1	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ GENERAL MYALGIA	28MAY2013 /1	29MAY2013 /-12	I	1	1	1	4	2
	Musculoskeletal and connective tissue disorders/ Flank pain/ RT.FLANK PAIN	28MAY2013 /1	29MAY2013 /-12	I	1	1	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0018/70 /F/A7/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	02JUL2013 /20	13JUL2013 /31	I	1	0	1	4	3
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	15JUN2013 /3	01JUL2013 /19	I	1	0	1	4	2
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	21JUN2013 /9	13JUL2013 /31	C	1	1	2	4	3
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	26JUN2013 /14	28JUN2013 /16	I	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0020/69 /M/A7/N	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	13APR2014 /298	02MAY2014 /-5	C	1	1	1	4	2
	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	29MAR2014 /283	07APR2014 /-30	C	1	1	1	5	2
	Gastrointestinal disorders/ Dyspepsia/ DYSPEPSIA	05MAR2014 /259	07MAR2014 /-61	C	1	1	1	4	1
	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	16JAN2014 /211	01FEB2014 /-95	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0020/69 /M/A7/N	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	18DEC2013 /182	Unknown/NA	I	6	1	1	4	1
	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	01NOV2013* /135	26NOV2013 /-162	C	1	1	1	4	2
	Gastrointestinal disorders/ Dental caries/ DENTAL CARIES	10OCT2013 /113	10OCT2013 /-209	C	1	2	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	30JUN2013 /11	22JUL2013 /-289	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0021/47 /M/A7/Y	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	13OCT2013 /116	15OCT2013 /-272	C	1	1	1	3	3
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	13OCT2013 /116	13OCT2013 /-274	C	1	1	1	3	2
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	04MAR2014 /258	03AUG2014 /20	I	1	1	1	4	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	04AUG2014 /411	04AUG2014 /21	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0021/47 /M/A7/Y	Gastrointestinal disorders/ Haematochezia/ HEMATOCHEZIA	04AUG2014 /411	02SEP2014 /50	I	1	1	2	4 [PD]	3
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	28JUL2014 /404	06AUG2014 /23	C	1	1	1	4	2
	Gastrointestinal disorders/ Haematochezia/ HEMATOCHEZIA	14JUL2014 /390	22JUL2014 /8	I	1	1	1	4	1
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	21JUL2014 /397	06AUG2014 /23	C	1	1	3 /21JUL2014 /Unknown	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0021/47 /M/A7/Y	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	14JUL2014 /390	20JUL2014 /6	C	1	1	1	3	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	09JUL2014 /385	13JUL2014 /-1	C	1	2	1	4	2
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	27JUN2014 /373	06AUG2014 /23	C	1	1	3 /27JUN2014 /14JUL2014	3	3
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	27JUN2014 /373	13JUL2014 /-1	C	1	1	3 /27JUN2014 /14JUL2014	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0021/47 /M/A7/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	01MAR2014 /255	02MAR2014 /-134	I	1	1	1	4	1
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	09JUN2014 /355	26JUN2014 /-18	C	1	1	1	3	2
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	28MAY2014 /343	26JUN2014 /-18	C	1	1	1	3	2
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	02JUN2014 /348	08JUN2014 /-36	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0021/47 /M/A7/Y	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	21MAY2014 /336	27MAY2014 /-48	C	1	1	3 /21MAY2014 /28MAY2014	3	3
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	14MAY2014 /329	01JUN2014 /-43	C	1	1	1	3	2
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	02MAY2014 /317	20MAY2014 /-55	C	1	1	1	3	2
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	23APR2014 /308	01MAY2014 /-74	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0021/47 /M/A7/Y	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	23APR2014 /308	13MAY2014 /-62	C	1	1	1	3	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	04APR2014 /289	Unknown/NA	I	6	1	1	4	2
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	09APR2014 /294	22APR2014 /-83	C	1	1	1	3	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	17MAR2014 /271	03APR2014 /-102	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0021/47 /M/A7/Y	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	08MAR2014 /262	22APR2014 /-83	C	1	1	1	3	2
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	26MAR2014 /280	08APR2014 /-97	C	1	1	1	3	1
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	17MAR2014 /271	25MAR2014 /-111	C	1	1	1	3	2
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	07MAR2014 /261	16MAR2014 /-120	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0021/47 /M/A7/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps) / Tumour haemorrhage/ INTRATUMORAL BLEEDING	01MAR2014 /255	11MAR2014 /-125	C	1	2	3 /03MAR2014 /12MAR2014	4 [CD]	3
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	02MAR2014 /256	02MAR2014 /-134	C	1	1	1	4	3
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	03MAR2014 /257	03MAR2014 /-133	C	1	1	1	4	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	22FEB2014 /248	08MAR2014 /-128	I	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0021/47 /M/A7/Y	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	24FEB2014 /250	07MAR2014 /-129	C	1	1	1	3	3
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	10FEB2014 /236	23FEB2014 /-141	C	1	1	1	3	2
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	05FEB2014 /231	09FEB2014 /-155	C	1	1	1	3	3
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	02MAR2014 /256	06MAR2014 /-130	C	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0021/47 /M/A7/Y	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	24FEB2014 /250	28FEB2014 /-136	C	1	1	1	3	2
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	01MAR2014 /255	01MAR2014 /-135	C	1	1	1	3	3
	Gastrointestinal disorders/ Abdominal pain lower/ ABDOMINAL PAIN(RIGHT LOWER QUATRANT)	26FEB2014 /252	10MAR2014 /-126	C	1	1	1	4	3
	Musculoskeletal and connective tissue disorders/ Flank pain/ RIGHT FLANK PAIN	11OCT2013 /114	25FEB2014 /-139	I	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0021/47 /M/A7/Y	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	05FEB2014 /231	23FEB2014 /-141	C	1	1	1	3	1
	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC SORENESS	23JAN2014 /218	Unknown/NA	I	6	1	1	4	1
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	29JAN2014 /224	04FEB2014 /-160	C	1	1	1	3	2
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	06JAN2014 /201	28JAN2014 /-167	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0021/47 /M/A7/Y	Skin and subcutaneous tissue disorders/ Pruritus/ LEFT ARM ITCHING	31DEC2013 /195	14JAN2014 /-181	I	1	0	1	4	1
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	30DEC2013 /194	05JAN2014 /-190	C	1	1	1	3	2
	Gastrointestinal disorders/ Haematochezia/ HEMATOCHEZIA	13JAN2014 /208	15JAN2014 /-180	I	1	2	1	4	1
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	18DEC2013 /182	29DEC2013 /-197	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0021/47 /M/A7/Y	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	11DEC2013 /175	04FEB2014 /-160	C	1	1	1	3	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	08DEC2013 /172	20MAR2014 /-116	C	1	1	1	4	1
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	27NOV2013 /161	10DEC2013 /-216	C	1	1	1	3	3
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	06DEC2013 /170	17DEC2013 /-209	C	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0021/47 /M/A7/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	09OCT2013 /112	10OCT2013 /-277	I	1	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	30OCT2013 /133	01NOV2013 /-255	C	1	1	1	3	2
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	06NOV2013 /140	26NOV2013 /-230	C	1	1	1	3	2
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	06NOV2013 /140	05DEC2013 /-221	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0021/47 /M/A7/Y	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	01NOV2013 /135	15DEC2013 /-211	C	1	1	1	4	1
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	23OCT2013 /126	05NOV2013 /-251	C	1	1	1	3	2
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	30OCT2013 /133	05NOV2013 /-251	C	1	1	1	3	3
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	16OCT2013 /119	29OCT2013 /-258	C	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0021/47 /M/A7/Y	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	14OCT2013 /117	22OCT2013 /-265	C	1	1	1	3	1
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	11OCT2013 /114	12OCT2013 /-275	C	1	1	1	3	2
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	11OCT2013 /114	12OCT2013 /-275	C	1	1	3 /11OCT2013 /16OCT2013	3	3
	Nervous system disorders/ Headache/ HEADACHE	09OCT2013 /112	10OCT2013 /-277	I	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0021/47 /M/A7/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	26AUG2013 /68	30AUG2013 /-318	I	1	1	1	4	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	31JUL2013 /42	31JUL2013 /-348	I	1	1	1	4	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	31JUL2013 /42	31JUL2013 /-348	I	1	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Flank pain/ FLANK PAIN	27JUN2013 /8	08JUL2013 /-371	I	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0021/47 /M/A7/Y	Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA	10JUL2013 /21	11JUL2013 /-368	I	1	1	1	2	1
	Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA	03JUL2013 /14	05JUL2013 /-374	I	1	1	1	3	1
	Gastrointestinal disorders/ Abdominal pain/ RIGHT ABDOMEN PAIN	27JUN2013 /8	08JUL2013 /-371	I	1	1	1	4	2
405-0022/65 /M/A7/N	Skin and subcutaneous tissue disorders/ Rash/ WHOLE BODY SKIN ERUPTION	18JUL2013 /14	24JUL2013 /-140	C	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0022/65 /M/A7/N	Skin and subcutaneous tissue disorders/ Rash/ SKIN ERUPTION	09OCT2013 /97	19OCT2013 /-53	C	1	1	1	4	2
	Gastrointestinal disorders/ Dyspepsia/ DYSPEPSIA	19SEP2013 /77	Unknown/NA	C	6	1	1	4	1
	Gastrointestinal disorders/ Gastric varices haemorrhage/ GASTRIC VARIX BLEEDING	25AUG2013 /52	28AUG2013 /-105	I	1	3	3 /28AUG2013 /04SEP2013	4[CD]	3
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIGHT SHOULDER PAIN	15AUG2013 /42	Unknown/NA	I	6	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0022/65 /M/A7/N	Gastrointestinal disorders/ Dyspepsia/ DYSPEPSIA	19AUG2013 /46	20AUG2013 /-113	I	1	0	1	4	1
	Eye disorders/ Eye disorder/ LEFT EYE DISORDER	09AUG2013 /36	13SEP2013 /-89	C	1	0	1	4	1
	Skin and subcutaneous tissue disorders/ Dermatitis allergic/ ALLEGIC SKIN ERUPTION	24JUL2013 /20	17SEP2013 /-85	C	1	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	20JUL2013 /16	31JUL2013 /-133	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0023/46 /M/A7/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	16AUG2013 /60	18AUG2013 /-15	I	1	1	1	4	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	17JUL2013 /30	18JUL2013 /-46	I	1	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ WHOLE BODY MYALGIA	21JUN2013 /4	23JUN2013 /-71	I	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ WHOLE BODY MYALGIA	18JUN2013 /1	21JUN2013 /-73	I	2	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0025/47 /M/A7/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ PROGRESSION OF NEOPLASTIC DISEASE LIVER	22JUL2013 /26	02AUG2013 /30	C	1	1	2	5 [PD]	3
	General disorders and administration site conditions/ Pyrexia/ FEVER	22JUL2013 /26	22JUL2013 /19	C	1	1	1	4	1
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	22JUL2013 /26	Unknown/NA	C	6	1	1	4 [PD]	3
	Renal and urinary disorders/ Chromaturia/ URINE DISCOLORATION	10JUL2013 /14	Unknown/NA	C	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0025/47 /M/A7/Y	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	10JUL2013 /14	24JUL2013 /21	C	1	1	1	4 [CD]	3
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ HEMOPTYSIS	04JUL2013 /8	06JUL2013 /3	I	1	1	1	4 [CD]	2
405-0028/67 /M/A7/N	Nervous system disorders/ Spinal cord compression/ SPINAL CORD COMPRESSION	10OCT2013 /78	24OCT2013 /22	C	3	1	1	5 [PD]	3
	Nervous system disorders/ Syncope/ SYNCOPE	02SEP2013 /40	02SEP2013 /-30	I	1	0	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0028/67 /M/A7/N	Nervous system disorders/ Spinal cord compression/ SPINAL CORD COMPRESSION	07OCT2013 /75	09OCT2013 /7	C	1	0	1	5	2
	Eye disorders/ Polypoidal choroidal vasculopathy/ POLYPOIDAL CHOROIDAL VASCULOPATHY,WET TYPE AGE-RELATED MACULAR DEGENERATION	02OCT2013 /70	Unknown/NA	C	6	3	3 /07OCT2013 /07OCT2013	4	3
	Psychiatric disorders/ Claustrophobia/ CLAUSTROPHOBIA	05SEP2013 /43	Unknown/NA	C	6	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Productive cough/ SPUTUM	26SEP2013 /64	Unknown/NA	I	6	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0028/67 /M/A7/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea exertional/ DYSPNEA ON EXERCISE	26SEP2013 /64	Unknown/NA	I	6	0	1	4	1
	Musculoskeletal and connective tissue disorders/ Back pain/ RIGHT LOWER BACK PAIN	16SEP2013 /54	Unknown/NA	I	6	1	1	4	2
	Skin and subcutaneous tissue disorders/ Skin irritation/ SKIN IRRITATION ON RT SITE	09SEP2013 /47	Unknown/NA	C	6	2	1	5	1
	Injury, poisoning and procedural complications/ Skin abrasion/ RIGHT CHEEK ABRASION	28AUG2013 /35	07SEP2013 /-25	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0028/67 /M/A7/N	Nervous system disorders/ Syncope/ SYNCOPE	28AUG2013 /35	28AUG2013 /-35	I	1	0	1	4	3
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	11AUG2013 /18	Unknown/NA	I	6	1	1	4	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	07AUG2013 /14	Unknown/NA	I	6	1	1	4	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	06AUG2013 /13	07AUG2013 /-56	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0028/67 /M/A7/N	Musculoskeletal and connective tissue disorders/ Neck pain/ WORSENING LEFT NECK PAIN	02AUG2013 /9	Unknown/NA	I	6	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ WORSENING LEFT SHOULDER PAIN	02AUG2013 /9	Unknown/NA	I	6	1	1	5	2
405-0030/35 /M/A7/Y	General disorders and administration site conditions/ Disease progression/ WORSENING OF HEPATOCELLULAR CARCINOMA	06OCT2013 /67	13OCT2013 /27	C	1	0	1	5[PD]	3
	Hepatobiliary disorders/ Hepatitis toxic/ TOXIC HEPATITIS	15OCT2013 /76	27OCT2013 /41	C	1	1	1	5[Unproven Wild Leave Extract]	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0030/35 /M/A7/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	13OCT2013 /74	Unknown/NA	C	6	0	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ BOTH LOWER EXTREMITY EDEMA	13OCT2013 /74	Unknown/NA	C	6	0	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	13OCT2013 /74	Unknown/NA	C	6	0	1	5	3
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE TRANSAMINASE INCREASED	18OCT2013 /79	Unknown/NA	C	6	0	1	4	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0030/35 /M/A7/Y	Investigations/ Aspartate aminotransferase increased/ ASPARTATE TRANSAMINASE INCREASED	04SEP2013 /35	17OCT2013 /31	C	1	0	1	4	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	04AUG2013 /4	07AUG2013 /-40	I	1	1	1	4 [CM]	3
	Gastrointestinal disorders/ Vomiting/ VOMITING	31JUL2013 /0	31JUL2013 /-47	I	1	0	1	5	1
405-0032/69 /M/A7/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	28AUG2014 /401	Unknown/NA	I	6	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0032/69 /M/A7/N	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ BLOOD TINGED SPUTUM	13AUG2014 /386	Unknown/NA	I	6	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ BLOOD TINGED SPUTUM	14JUL2014 /356	14JUL2014 /-53	I	1	0	1	4	1
	Eye disorders/ Cataract/ OCULUS DEXTER CATARACT	11JUN2014 /323	12JUN2014 /-85	C	1	2	1	5[CD]	3
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ BLOOD TINGED SPUTUM	06JUN2014 /318	09JUN2014 /-88	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0032/69 /M/A7/N	Eye disorders/ Cataract/ OCULUS DEXTER CATARACT	20MAY2014 /301	10JUN2014 /-87	C	1	3	1	5	3
	Eye disorders/ Cataract/ OCULUS SINISTER CATARACT	20MAY2014 /301	21MAY2014 /-107	C	1	2	3 /26MAY2014 /02JUN2014	5[CD]	3
	Eye disorders/ Cataract/ OCULUS DEXTER/OCULUS SINISTER CATARACT	14APR2014 /265	19MAY2014 /-109	C	1	2	1	5	3
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Meningioma/ MENINGIOMA	04MAR2014 /224	Unknown/NA	C	6	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0032/69 /M/A7/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	03FEB2014 /195	20FEB2014 /-197	I	1	1	1	4	2
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Meningioma/ MENINGIOMA	24JAN2014 /185	28FEB2014 /-189	I	1	1	1	4	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	09JAN2014 /170	Unknown/NA	C	6	1	1	4	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	21NOV2013 /121	08JAN2014 /-240	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0032/69 /M/A7/N	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Meningioma/ MENINGIOMA	26DEC2013 /156	23JAN2014 /-225	I	1	1	1	4	1
	General disorders and administration site conditions/ Localised oedema/ LOCALIZED EDEMA	06DEC2013 /136	15DEC2013 /-264	C	1	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT KNEE PAIN	18NOV2013 /118	28MAY2014 /-100	I	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Dysphonia/ VOICE ALTERATION	27OCT2013 /96	13NOV2013 /-296	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0032/69 /M/A7/N	Gastrointestinal disorders/ Oral pain/ ORAL PAIN	16OCT2013 /85	31DEC2013 /-248	I	1	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT KNEE PAIN	13SEP2013 /52	16SEP2013 /-354	I	1	0	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	22SEP2013 /61	20NOV2013 /-289	C	1	1	1	4	2
	Musculoskeletal and connective tissue disorders/ Arthritis/ ARTHRITIS	17SEP2013 /56	22AUG2014 /-14	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0032/69 /M/A7/N	Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT KNEE PAIN	17SEP2013 /56	17NOV2013 /-292	I	1	1	1	5	1
	Gastrointestinal disorders/ Oral pain/ ORAL PAIN	14AUG2013 /22	17SEP2013 /-353	I	1	1	1	4	1
405-0033/43 /M/A7/N	Respiratory, thoracic and mediastinal disorders/ Sputum discoloured/ SPUTUM (WHITISH)	16OCT2013 /69	Unknown/NA	I	6	1	1	4	1
	Investigations/ Neutrophil count decreased/ NEUTROPHIL COUNT DECREASED	23OCT2013 /76	05NOV2013 /13	I	1	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0033/43 /M/A7/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	19SEP2013 /42	22SEP2013 /-31	I	1	1	1	4	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	23SEP2013 /46	25SEP2013 /-28	I	1	0	1	4	1
	Investigations/ Neutrophil count decreased/ NEUTROPHIL COUNT DECREASED	25SEP2013 /48	01OCT2013 /-22	I	1	0	3 /25SEP2013 /02OCT2013	4	3
	General disorders and administration site conditions/ Fatigue/ FATIGUE	07SEP2013 /30	07SEP2013 /-46	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0033/43 /M/A7/N	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	28AUG2013 /20	24SEP2013 /-29	I	1	0	1	4	2
	General disorders and administration site conditions/ Injection site oedema/ INJECTION SITE EDEMA	23AUG2013 /15	23AUG2013 /-61	I	1	0	1	2	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	10AUG2013 /2	10AUG2013 /-74	I	1	0	1	2	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ MAYLGIA	10AUG2013 /2	10AUG2013 /-74	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0034/61 /M/A7/N	Gastrointestinal disorders/ Abdominal pain lower/ RIGHT LOW QUADRANT PAIN	11NOV2013 /95	Unknown/NA	I	6	1	1	4	2
	Musculoskeletal and connective tissue disorders/ Flank pain/ RIGHT FLANK PAIN	11NOV2013 /95	Unknown/NA	I	6	1	1	4	2
	Musculoskeletal and connective tissue disorders/ Back pain/ RIGHT BACK PAIN	12SEP2013 /35	10NOV2013 /18	I	1	0	1	4	1
405-0035/66 /M/A7/Y	Gastrointestinal disorders/ Haematochezia/ HEMATOCHEZIA	22OCT2013 /64	05NOV2013 /25	I	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0035/66 /M/A7/Y	Gastrointestinal disorders/ Haematochezia/ HEMATOCHEZIA	18OCT2013 /60	21OCT2013 /10	I	1	1	1	4 [PD]	2
	Metabolism and nutrition disorders/ Hypophosphataemia/ HYPOPHOSPHATEMIA	11OCT2013 /53	Unknown/NA	C	6	1	1	4	2
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	02OCT2013 /44	Unknown/NA	I	6	1	1	4	2
	Gastrointestinal disorders/ Haematochezia/ HEMATOCHEZIA	08SEP2013 /20	17OCT2013 /6	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0035/66 /M/A7/Y	Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA	19AUG2013 /0	20AUG2013 /-52	I	1	0	1	3	1
405-0039/73 /M/A7/N	General disorders and administration site conditions/ Oedema/ BOTH LEG PITTING EDEMA	15DEC2013 /93	Unknown/NA	C	6	0	1	4	1
	Skin and subcutaneous tissue disorders/ Rash generalised/ SKIN RASH ON WHOLE BODY	21OCT2013 /38	21OCT2013 /-39	I	1	0	1	3	1
405-0040/65 /M/A7/N	Nervous system disorders/ Carpal tunnel syndrome/ RIGHT CARPAL TUNNEL SYNDROME	10DEC2013 /78	Unknown/NA	I	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0040/65 /M/A7/N	Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT FINGER PAIN	20NOV2013 /58	09DEC2013 /0	I	1	0	1	4	1
	Skin and subcutaneous tissue disorders/ Rash generalised/ WHOLE BODY RASH	01OCT2013 /8	11OCT2013 /-59	I	1	0	1	3	2
405-0042/53 /M/A7/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ PROGRESSION OF NEOPLASTIC DISEASE-LIVER	26DEC2013 /83	26DEC2013 /29	C	4	0	1	5[PD]	5
	Musculoskeletal and connective tissue disorders/ Flank pain/ RIGHT FLANK PAIN	25NOV2013 /52	Unknown/NA	I	6	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0042/53 /M/A7/Y	Skin and subcutaneous tissue disorders/ Rash/ BOTH LEGS SKIN RASH	01NOV2013* /28	25NOV2013 /-2	C	1	0	1	4	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	06OCT2013 /2	Unknown/NA	I	6	1	1	3	1
	Psychiatric disorders/ Mood altered/ MOOD CHANGE	06OCT2013 /2	Unknown/NA	I	6	0	1	3	1
405-0043/49 /M/A7/Y	Gastrointestinal disorders/ Abdominal distension/ EPIGASTRIC DISTENSION	21NOV2013 /56	21NOV2013 /-7	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0043/49 /M/A7/Y	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	21NOV2013 /56	21NOV2013 /-7	C	1	0	1	4	1
	Eye disorders/ Visual impairment/ VISUAL DISTURVANCE	01DEC2013 /66	Unknown/NA	I	6	0	1	4	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENTION	21NOV2013 /56	21NOV2013 /-7	C	1	0	2	4[PD]	3
	Skin and subcutaneous tissue disorders/ Skin lesion/ SCALP LESION	15NOV2013 /50	Unknown/NA	C	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0043/49 /M/A7/Y	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	03DEC2013 /68	Unknown/NA	I	6	1	1	4	1
	Nervous system disorders/ Headache/ HEADACHE	01NOV2013 /36	Unknown/NA	I	6	0	1	4	2
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	31OCT2013 /35	Unknown/NA	I	6	1	1	4	2
	Psychiatric disorders/ Insomnia/ INSOMNIA	01NOV2013 /36	Unknown/NA	I	6	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0043/49 /M/A7/Y	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	17OCT2013 /21	24OCT2013 /-35	I	2	0	1	4	1
	Infections and infestations/ Rhinitis/ RHINITIS	05OCT2013 /9	17OCT2013 /-42	I	1	1	1	4	1
	Skin and subcutaneous tissue disorders/ Rash generalised/ RASH ON WHOLE BODY	26SEP2013 /0	27SEP2013 /-62	I	1	0	1	2	1
501-0001/59 /M/A1/N	Gastrointestinal disorders/ Ascites/ ASCITES	23JAN2014 /71	26MAY2014 /124	C	1	0	1	5 [PD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0001/59 /M/A1/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	16JAN2014 /64	26MAY2014 /124	I	1	1	1	5[Hcc]	1
	Respiratory, thoracic and mediastinal disorders/ Oropharyngeal discomfort/ PHARYNGALGIA	26JAN2014 /74	26MAY2014 /124	C	1	1	1	5[Consider That This Ae Was Related With The Reaction After Cough.]	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	25JAN2014 /73	26MAY2014 /124	C	1	0	1	5[Consider That This Ae Was Related With Liver Diseases]	1
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	01JAN2014 /49	26MAY2014 /124	C	1	1	1	5[Hcc]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0001/59 /M/A1/N	Vascular disorders/ Hypertension/ HYPERTENSION	20NOV2013 /7	02JAN2014 /-20	C	1	0	1	3	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	16JAN2014 /64	22JAN2014 /0	I	1	0	1	5[Hcc]	1
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ BLOOD-STAINED SPUTUM	16JAN2014 /64	26MAY2014 /124	I	1	1	1	5	1
501-0002/36 /F/A1/N	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	23DEC2013 /21	27DEC2013 /-46	C	2	1	1	5[Hcc Related]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0002/36 /F/A1/N	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	23DEC2013 /21	27DEC2013 /-46	C	1	1	1	5[Hcc Related]	2
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	20JAN2014 /49	07FEB2014 /-4	C	1	1	1	5[Hcc Related]	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	09DEC2013 /7	23DEC2013 /-50	C	2	0	1	5[Hcc Related.]	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	27DEC2013 /25	20JAN2014 /-22	C	2	1	1	5[Hcc Related]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0005/80 /M/A1/N	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	26JUN2015 /519	Unknown/NA	C	2	0	1	5 [Hcc]	1
	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	12MAR2015 /413	27MAR2015 /-62	C	1	0	1	4 [Hcc]	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	26FEB2015 /399	27MAR2015 /-62	C	1	0	1	4 [Hcc]	2
	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	27MAR2014 /63	10APR2014 /-413	C	1	0	1	4 [Hcc]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0005/80 /M/A1/N	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	29JAN2015 /371	10FEB2015 /-107	C	1	0	1	4 [Hcc]	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	31DEC2014 /342	15JAN2015 /-133	C	1	0	1	4 [Hcc]	1
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	13FEB2014 /21	26FEB2014 /-456	C	1	0	1	4 [Hcc]	1
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	29JAN2014 /6	07FEB2014 /-475	C	1	0	1	4 [Hcc]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0005/80 /M/A1/N	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	23OCT2014 /273	04DEC2014 /-175	C	1	0	1	4 [Hcc]	1
	Investigations/ Blood bilirubin increased/ TOTAL BILIRUBIN INCREASED	29AUG2014 /218	24SEP2014 /-246	C	1	0	1	4 [Hcc]	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	01AUG2014 /190	15AUG2014 /-286	C	1	0	1	4 [Hcc]	1
	Investigations/ Blood bilirubin increased/ TOTAL BILIRUBIN INCREASED	03JUL2014 /161	18JUL2014 /-314	C	1	0	1	4 [Hcc]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0005/80 /M/A1/N	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	06JUN2014 /134	03JUL2014 /-329	C	1	0	1	4 [Hcc]	1
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	09MAY2014 /106	23MAY2014 /-370	C	1	0	1	4 [Hcc]	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	10APR2014 /77	23MAY2014 /-370	C	1	0	1	4 [Hcc]	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	26FEB2014 /34	14MAR2014 /-440	C	2	0	1	4 [Hcc]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0005/80 /M/A1/N	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	10APR2014 /77	25APR2014 /-398	C	1	0	1	4[Hcc]	1
	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	13FEB2014 /21	14MAR2014 /-440	C	1	0	1	4[Hcc]	1
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	10APR2014 /77	25APR2014 /-398	C	1	0	1	4[Hcc]	1
	Investigations/ Blood bilirubin increased/ TOTAL BILIRUBIN INCREASED	27MAR2014 /63	10APR2014 /-413	C	1	0	1	4[Hcc]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0005/80 /M/A1/N	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED.	29JAN2014 /6	07FEB2014 /-475	C	1	0	1	4 [Hcc]	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	13FEB2014 /21	26FEB2014 /-456	C	2	0	1	4 [Hcc]	2
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	27MAR2014 /63	10APR2014 /-413	C	1	0	1	4 [Hcc]	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	14MAR2014 /50	10APR2014 /-413	C	2	0	1	4 [Hcc]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0006/60 /M/A1/Y	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	05MAY2014 /81	18NOV2014 /208	C	1	1	1	5[Hcc]	2
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	03APR2014 /49	17APR2014 /-7	C	2	1	1	5[Hcc]	1
	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	17APR2014 /63	28APR2014 /4	C	1	0	1	5[Hcc]	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	04MAY2014 /80	04MAY2014 /10	C	1	1	1	5[CM]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0006/60 /M/A1/Y	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	28APR2014 /74	05MAY2014 /11	C	2	1	1	5[Hcc]	1
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	20MAR2014 /35	03APR2014 /-21	C	2	1	1	5[Hcc]	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	04MAY2014 /80	18NOV2014 /208	C	1	1	1	5[CM]	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	04MAY2014 /80	18NOV2014 /208	C	1	1	1	5[CM]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0006/60 /M/A1/Y	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	20FEB2014 /7	03APR2014 /-21	C	1	0	1	5[Hcc]	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	04MAY2014 /80	18NOV2014 /208	C	1	0	1	5[CM]	1
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	17APR2014 /63	28APR2014 /4	C	2	1	1	5[Hcc]	2
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	05MAY2014 /81	18NOV2014 /208	C	1	1	1	5[Hcc]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0006/60 /M/A1/Y	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	05MAY2014 /81	18NOV2014 /208	C	1	1	1	5[Hcc]	1
501-0008/76 /F/A1/N	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	10JUL2014 /86	12JUL2014 /17	C	1	1	1	5[It Is RelatedWith Insufficien cy Of Intake.]	3
	Infections and infestations/ Lung infection/ PULMONARY INFECTION	28JUN2014 /74	15JUL2014 /20	C	2	1	1	5[It Is RelatedWith Tumor Appression. ]	3
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	26MAY2014 /41	11JUL2014 /16	C	2	0	1	5[It Is RelatedWith Lung Metastases. ]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0008/76 /F/A1/N	Metabolism and nutrition disorders/ Decreased appetite/ INAPPETENCE	05JUL2014 /81	Unknown/NA	C	6	1	1	5[It Is RelatedWith Liver Cancer.]	1
	Infections and infestations/ Lung infection/ PULMONARY INFECTION	15JUL2014 /91	Unknown/NA	C	6	1	1	5	2
	General disorders and administration site conditions/ Catheter site injury/ SKIN INJURY OF SITE OF PUNCTURE BECAUSE OF POTASSIUM CHLORIDE EXOSMOSIS	10JUL2014 /86	10JUL2014 /15	I	1	1	1	5[It Is RelatedWith Venipunctur e.]	1
501-0009/62 /M/A1/Y	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	18OCT2014 /92	Unknown/NA	C	6	1	1	5[CD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0009/62 /M/A1/Y	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	19SEP2014 /63	30SEP2014 /4	C	2	0	1	5 [CD]	1
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	18OCT2014 /92	Unknown/NA	C	6	1	1	5 [CD]	2
	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	08AUG2014 /21	22AUG2014 /-35	C	1	1	1	5 [CD]	2
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	03OCT2014 /77	08OCT2014 /12	C	2	1	1	5 [CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0009/62 /M/A1/Y	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	08AUG2014 /21	22AUG2014 /-35	C	1	0	1	5 [CD]	2
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	02OCT2014 /76	03OCT2014 /7	C	2	1	1	5 [CD]	2
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	02OCT2014 /76	03OCT2014 /7	C	1	0	1	5 [CD]	3
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	01OCT2014 /75	02OCT2014 /6	C	2	1	1	5 [CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0009/62 /M/A1/Y	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	01OCT2014 /75	03OCT2014 /7	C	1	1	1	5 [CD]	3
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	30SEP2014 /74	02OCT2014 /6	C	2	0	1	5 [CD]	4
	Blood and lymphatic system disorders/ Hypersplenism/ HYPERSPLENISM	30SEP2014 /74	01OCT2014 /5	C	2	1	1	5 [CD]	4
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	30SEP2014 /74	01OCT2014 /5	C	2	1	1	5 [CD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0009/62 /M/A1/Y	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	05SEP2014 /49	09SEP2014 /-17	C	1	0	3 /05SEP2014 /09SEP2014	5 [CD]	4
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	19SEP2014 /63	30SEP2014 /4	C	2	1	1	5 [CD]	1
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	05SEP2014 /49	19SEP2014 /-7	C	2	1	1	5 [CD]	2
	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	05SEP2014 /49	09SEP2014 /-17	C	1	1	3 /05SEP2014 /09SEP2014	5 [CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0009/62 /M/A1/Y	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	08AUG2014 /21	05SEP2014 /-21	C	2	1	1	5 [CD]	1
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	25JUL2014 /7	08AUG2014 /-49	C	2	1	1	5 [CD]	2
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	25JUL2014 /7	08AUG2014 /-49	C	2	1	1	5 [CD]	1
	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	19SEP2014 /63	30SEP2014 /4	C	2	0	1	5 [CD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0009/62 /M/A1/Y	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	18JUL2014 /0	25JUL2014 /-63	C	2	1	1	5 [CD]	1
	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	18JUL2014 /0	08AUG2014 /-49	C	2	1	1	5 [CD]	1
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	08OCT2014 /82	18OCT2014 /22	C	2	1	1	5 [CD]	1
	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	30SEP2014 /74	01OCT2014 /5	C	2	1	1	5 [CD]	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0009/62 /M/A1/Y	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	18OCT2014 /92	Unknown/NA	C	6	1	1	5[CD]	1
501-0010/65 /M/A1/Y	Investigations/ Blood bilirubin increased/ TOTAL BILIRUBIN INCREASED	27NOV2014 /78	02DEC2014 /20	C	1	1	1	5[Hcc]	1
	Investigations/ Bilirubin conjugated increased/ DIRECT BILIRUBIN INCREASED	28SEP2014 /18	14OCT2014 /-29	C	1	1	1	5[Hcc]	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	11NOV2014 /62	27NOV2014 /15	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0010/65 /M/A1/Y	Investigations/ Blood bilirubin increased/ TOTAL BILRUBIN INCREASED	28SEP2014 /18	14OCT2014 /-29	C	1	1	1	5[Hcc]	1
	Investigations/ Alanine aminotransferase increased/ ALT INCREASE	27NOV2014 /78	02DEC2014 /20	C	1	0	1	5[Hcc]	1
	Blood and lymphatic system disorders/ Leukopenia/ LEUCOPENIA	14OCT2014 /34	11NOV2014 /-1	C	1	1	1	3	1
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	15NOV2014 /66	27NOV2014 /15	C	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0010/65 /M/A1/Y	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	14OCT2014 /34	11NOV2014 /-1	C	2	1	1	3	2
	Skin and subcutaneous tissue disorders/ Dermatitis acneiform/ ACNEIFORM RASH	15NOV2014 /66	03DEC2014 /21	C	1	1	3 /18NOV2014 /26NOV2014	3	3
502-0002/65 /M/A1/N	Musculoskeletal and connective tissue disorders/ Muscle twitching/ RIGHT LEG TWITCH	14JAN2014 /4	15JAN2014 /5	I	1	1	1	5 [CD]	2
	Respiratory, thoracic and mediastinal disorders/ Respiratory failure/ RESPIRATORY FAILURE	19JAN2014 /9	19JAN2014 /9	I	4	1	1	5 [CD]	5

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
502-0002/65 /M/A1/N	Respiratory, thoracic and mediastinal disorders/ Respiratory failure/ RESPIRATORY FAILURE	16JAN2014 /6	18JAN2014 /8	C	1	3	2	5 [CD]	4
503-0001/32 /M/A1/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	02JAN2014 /24	02JAN2014 /2	I	1	1	1	2	1
	Respiratory, thoracic and mediastinal disorders/ Pulmonary congestion/ CHEST STUFLY	23DEC2013 /14	14FEB2014 /45	I	1	0	1	5 [CD]	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	13DEC2013 /4	20DEC2013 /-11	I	1	1	1	2	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
503-0001/32 /M/A1/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	11DEC2013 /2	16DEC2013 /-15	I	1	0	1	3	1
503-0004/49 /M/A1/Y	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	18MAR2014 /7	05APR2014 /11	C	1	0	1	4 [CD]	1
	Investigations/ Platelet count decreased/ LOW PLATELET COUNT	15MAR2014 /4	05APR2014 /11	C	1	0	1	4 [CD]	2
	Gastrointestinal disorders/ Vomiting/ VOMIT	22MAR2014 /11	05APR2014 /11	I	1	1	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
503-0004/49 /M/A1/Y	Gastrointestinal disorders/ Vomiting/ VOMIT	12MAR2014 /1	22MAR2014 /-3	I	1	1	1	2	2
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	12MAR2014 /1	24MAR2014 /-1	I	1	1	1	4 [CM]	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	14MAR2014 /3	24MAR2014 /-1	I	1	1	1	5 [Related To Cancer Of The Liver Disease.]	2
	Renal and urinary disorders/ Oliguria/ OLIGURESIS	14MAR2014 /3	21MAR2014 /-4	I	1	1	1	4 [The Reason Should Be Cancer Of The Liver Disease Related And Cirrhosis Of The Liver.]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
503-0004/49 /M/Al/Y	Hepatobiliary disorders/ Liver injury/ LIVER FUNCTION DAMAGE	22MAR2014 /11	05APR2014 /11	C	4	1	2	4[Caused By Tumor Or Hepatitis]	5
503-0006/54 /M/Al/Y	Investigations/ Platelet count decreased/ LOW PLATELET COUNT	19OCT2014 /74	Unknown/NA	C	2	0	1	4[Related To Hcc]	2
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	31DEC2014 /147	15JAN2015 /-43	C	1	0	1	4[Related To Hcc]	1
	Investigations/ Bilirubin conjugated increased/ DIRECT BILIRUBIN INCREASED	05NOV2014 /91	15JAN2015 /-43	C	1	0	1	4[Related To Hcc]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
503-0006/54 /M/A1/Y	Investigations/ Neutrophil count decreased/ NEUTROPHILS REDUCED	25SEP2014 /50	08OCT2014 /-142	C	1	0	1	4[Related To Hcc]	1
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	25SEP2014 /50	Unknown/NA	C	2	0	1	4[Related To Hcc]	1
	Investigations/ Blood bilirubin unconjugated increased/ INDIRECT BILIRUBIN INCREASED	22OCT2014 /77	05NOV2014 /-114	C	1	0	1	4[Related To Hcc]	2
	Investigations/ Platelet count decreased/ LOW PLATELET COUNT	22OCT2014 /77	19NOV2014 /-100	C	2	0	1	4[CD]	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
503-0006/54 /M/A1/Y	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	13AUG2014 /7	22OCT2014 /-128	C	2	0	1	4 [CD]	3
503-0007/57 /M/A1/N	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	18NOV2014 /21	Unknown/NA	C		0	1	4 [Related To Hcc]	3
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	18NOV2014 /21	16DEC2014 /-28	C	2	0	1	4 [Related To Hcc]	3
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	04NOV2014 /7	18NOV2014 /-56	C	2	0	1	4 [Related To Hcc]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
503-0007/57 /M/A1/N	Investigations/ White blood cell count decreased/ WHITE BLOOD CELLS DECLINE	18NOV2014 /21	Unknown/NA	C	2	0	1	4[Related To Hcc]	2
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELLS DECLINE	04NOV2014 /7	18NOV2014 /-56	C	2	0	1	4[Related To Hcc]	1
503-0008/50 /M/A1/Y	Investigations/ Aspartate aminotransferase increased/ ASPERTATE AMINOTRANSFERASE INCREASED	10DEC2014 /41	30APR2015 /141	C	1	0	1	4[Disease Association ]	3
	Investigations/ Aspartate aminotransferase increased/ ASPERTATE AMINOTRANSFERASE INCREASED	19NOV2014 /20	10DEC2014 /0	C	2	0	1	4[Disease Association ]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
503-0009/57 /M/A1/N	Investigations/ Platelet count decreased/ PLATELET DECLINE	26NOV2014 /7	29NOV2014 /3	C	1	0	1	4[Related To Hcc]	2
	Investigations/ Blood bilirubin unconjugated increased/ INDIRECT BILIRUBIN INCREASED	26NOV2014 /7	29NOV2014 /3	C	1	0	1	4[Related To Hcc]	2
	Investigations/ Neutrophil percentage increased/ NEUTROPHIL PERCENTAGE INCREASED	26NOV2014 /7	29NOV2014 /3	C	1	0	1	4[Related To Hcc]	1
	Investigations/ Blood creatinine increased/ CREATININE INCREASED	26NOV2014 /7	29NOV2014 /3	C	1	0	1	4[Related To Hcc]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
503-0009/57 /M/A1/N	Investigations/ Bilirubin conjugated increased/ DIRECT BILIRUBIN INCREASED	26NOV2014 /7	29NOV2014 /3	C	1	0	1	4[Related To Hcc]	2
	Investigations/ Blood albumin decreased/ ALBUMIN DECLINE	26NOV2014 /7	29NOV2014 /3	C	1	0	1	4[Related To Hcc]	2
	Investigations/ Red blood cell count decreased/ RED BLOOD CELLS DECLINE	26NOV2014 /7	29NOV2014 /3	C	1	0	1	4[Related To Hcc]	2
	Investigations/ Haemoglobin decreased/ HEMOGLOBIN DECREASED	26NOV2014 /7	29NOV2014 /3	C	1	0	1	4[Related To Hcc]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
503-0009/57 /M/A1/N	Investigations/ Blood urea increased/ UREA NITROGEN INCREASED	26NOV2014 /7	29NOV2014 /3	C	1	0	1	4[Related To Hcc]	2
	Investigations/ Aspartate aminotransferase increased/ ASPERTATE AMINOTRANSFERASE INCREASED	26NOV2014 /7	29NOV2014 /3	C	1	0	1	4[Related To Hcc]	1
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Hepatic neoplasm/ NODULES OF LIVER CANCER RUPTURE	29NOV2014 /10	29NOV2014 /3	I	4	0	2	5[PD]	5
504-0001/47 /M/A1/N	Investigations/ Blood alkaline phosphatase increased/ ALP INCREASED	11MAR2014 /22	06MAY2014 /-35	C	2	0	1	5[Disease Association ]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
504-0001/47 /M/A1/N	Investigations/ Blood bilirubin increased/ ELEVATED BILIRUBIN	20MAY2014 /92	03JUN2014 /-7	C	1	0	1	5[Disease Association ]	3
	Investigations/ Blood bilirubin increased/ ELEVATED BILIRUBIN	11MAR2014 /22	20MAY2014 /-21	C	2	0	1	5[Disease Association ]	2
	Investigations/ Blood bilirubin increased/ ELEVATED BILIRUBIN	25FEB2014 /8	11MAR2014 /-91	C	2	0	1	5[Disease Association ]	1
	Investigations/ Alanine aminotransferase increased/ INCREASED ALT	08APR2014 /50	Unknown/NA	C	5	0	1	5[Disease Association ]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
504-0001/47 /M/A1/N	Investigations/ Alanine aminotransferase increased/ INCREASED ALT	11MAR2014 /22	25MAR2014 /-77	C	1	0	1	5[Disease Association ]	1
	Investigations/ Aspartate aminotransferase increased/ INCREASED AST	08APR2014 /50	03JUN2014 /-7	C	2	0	1	5[Disease Association ]	2
	Investigations/ Activatedpartial thromboplastin time prolonged/ APTT PROLONG	20MAY2014 /92	03JUN2014 /-7	C	1	0	1	5[Disease Association ]	1
	Investigations/ Activatedpartial thromboplastin time prolonged/ APTT PROLONG	25FEB2014 /8	08APR2014 /-63	C	1	0	1	5[Disease Association ]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
504-0001/47 /M/A1/N	Investigations/ International normalised ratio increased/ INR PROLONG	11MAR2014 /22	08APR2014 /-63	C	1	0	1	5[Disease Association ]	1
	Investigations/ Platelet count decreased/ LOW PLATELETS	25MAR2014 /36	06MAY2014 /-35	C	1	1	1	5[Disease Association ]	2
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ ALBUMIN DEFICIENCY	20MAY2014 /92	27JUL2014 /47	I	1	0	1	5[PD]	1
	Investigations/ Blood bilirubin increased/ ELEVATED BILIRUBIN	03JUN2014 /106	Unknown/NA	C	5	0	1	5[Disease Association ]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
504-0001/47 /M/A1/N	Investigations/ International normalised ratio increased/ INR PROLONG	06MAY2014 /78	20MAY2014 /-21	C	1	0	1	5[Disease Association ]	1
	Investigations/ Aspartate aminotransferase increased/ INCREASED AST	03JUN2014 /106	Unknown/NA	C	5	0	1	5[Disease Association ]	3
	Investigations/ Gamma-glutamyltransferase increased/ ELEVATED GGT	06MAY2014 /78	Unknown/NA	C	5	0	1	5[Disease Association ]	3
	Investigations/ Gamma-glutamyltransferase increased/ ELEVATED GGT	08APR2014 /50	22APR2014 /-49	C	1	0	1	5[Disease Association ]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
504-0001/47 /M/A1/N	Investigations/ Blood alkaline phosphatase increased/ ALP INCREASED	06MAY2014 /78	Unknown/NA	C	5	0	1	5[Disease Association ]	2
504-0007/32 /M/A1/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	11OCT2014 /0	31OCT2014 /14	I	1	1	1	4[RelatedTo Tumor]	2
	Investigations/ Gamma-glutamyltransferase increased/ GGT RISE	17OCT2014 /6	31OCT2014 /14	C	1	0	1	5[RelatedTo Tumor]	3
	Investigations/ Blood alkaline phosphatase increased/ ALP RISE	17OCT2014 /6	31OCT2014 /14	C	1	0	1	4[RelatedTo Tumor]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
504-0007/32 /M/A1/N	General disorders and administration site conditions/ Disease progression/ DISEASE PROGRESSION	31OCT2014 /20	31OCT2014 /14	C	4	0	1	4 [PD]	5
505-0001/70 /M/A1/N	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	18JAN2015 /145	24JAN2015 /130	C	1	1	1	5 [CD]	3
	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	15OCT2014 /50	18JAN2015 /124	C	1	1	1	5 [CD]	2
	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	15OCT2014 /50	22DEC2014 /97	C	1	0	1	5 [CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
505-0001/70 /M/A1/N	General disorders and administration site conditions/ Peripheral swelling/ SWELLING OF THE LIMBS	19SEP2014 /24	24JAN2015 /130	C	1	1	1	5 [CD]	2
	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	15OCT2014 /50	Unknown/NA	C	6	1	1	5 [CD]	2
	Blood and lymphatic system disorders/ Leukocytosis/ LEUKOCYTOSIS	16SEP2014 /21	17NOV2014 /62	I	1	0	1	5 [May Be Associated With Intestinal Infection.]	1
	Metabolism and nutrition disorders/ Hypocalcaemia/ HYPOCALCEMIA	29SEP2014 /34	22DEC2014 /97	C	1	1	1	5 [CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
505-0001/70 /M/A1/N	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPALBUMINEMIA	16SEP2014 /21	24JAN2015 /130	C	1	1	1	5[CD]	2
	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	22SEP2014 /27	29SEP2014 /13	C	1	0	1	5[CD]	1
	Investigations/ Neutrophil count increased/ NEUTROPHIL COUNT INCREASED	16SEP2014 /21	28OCT2014 /42	C	1	1	1	5[Intestina l Infection]	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	16SEP2014 /21	20SEP2014 /4	C	1	1	1	5[Intestina l Infection]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
505-0001/70 /M/A1/N	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	16SEP2014 /21	15OCT2014 /29	C	1	1	1	5 [CD]	1
	Metabolism and nutrition disorders/ Hypocalcaemia/ HYPOCALCEMIA	22SEP2014 /27	29SEP2014 /13	C	1	1	1	5 [CD]	2
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	22SEP2014 /27	29SEP2014 /13	C	1	1	1	5 [CD]	3
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	29SEP2014 /34	15OCT2014 /29	C	1	1	1	5 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
505-0001/70 /M/A1/N	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	22SEP2014 /27	29SEP2014 /13	C	2	1	3 /23SEP2014 /Unknown	5[CD]	3
	Infections and infestations/ Gastrointestinal infection/ GASTROINTESTINAL INFECTION	15SEP2014 /20	30SEP2014 /14	I	1	0	1	5[May Be Assomay Be Associated With Drinking Unclean Food.]	1
	Infections and infestations/ Gastroenteritis/ ACUTE GASTROENTERITIS	18SEP2014 /23	30SEP2014 /14	I	1	1	1	4[Unhygieni c Food]	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	15SEP2014 /20	16SEP2014 /0	I	1	0	1	5[May Be Associated With Drinking Unclean Food.]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
506-0002/54 /M/A1/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	25OCT2014 /166	29APR2015 /22	I	1	1	1	4 [CD]	1
	Investigations/ Blood bilirubin increased/ ELEVATED TOTAL BILIRUBIN	26FEB2015 /290	07APR2015 /0	C	1	0	1	5 [CD]	1
	Metabolism and nutrition disorders/ Hypoproteinaemia/ HYPOPROTEINEMIA	11FEB2015 /275	Unknown/NA	C	6	0	1	5 [CD]	1
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	31DEC2014 /233	14JAN2015 /-83	C	2	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
506-0002/54 /M/A1/Y	Investigations/ Blood triglycerides increased/ ELEVATED TRIGLYCERIDES	13AUG2014 /93	10SEP2014 /-209	C	1	0	1	5[Related To Metabolism Of Diet]	1
	Investigations/ Blood triglycerides increased/ ELEVATED TRIGLYCERIDES	16JUL2014 /65	06AUG2014 /-244	C	1	0	1	5[Related To Metabolism Of Diet]	1
	Investigations/ Blood triglycerides increased/ ELEVATED TRIGLYCERIDES	19MAY2014 /7	16JUN2014 /-295	C	1	0	1	5[Related To Metabolism Of Diet]	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN WORSE	12AUG2014 /92	Unknown/NA	C	6	1	1	5[CD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
506-0003/66 /M/A1/N	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	30OCT2014 /50	05NOV2014 /14	C	1	0	1	5[Get Cold]	1
506-0004/49 /M/A1/Y	Investigations/ Blood albumin decreased/ ALBUMIN DECREASED	24DEC2014 /58	15FEB2015 /60	C	1	0	1	5[Malnutrit ion]	1
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	05NOV2014 /9	15FEB2015 /60	C	1	0	1	5[CD]	1
	Investigations/ Gamma-glutamyltransferase increased/ GGT INCREASED	05NOV2014 /9	19NOV2014 /-28	C	1	0	1	5[CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
506-0004/49 /M/A1/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	23DEC2014 /57	03JAN2015 /17	I	1	1	1	4 [PD]	1
508-0001/36 /M/A1/Y	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	27JAN2014 /19	08FEB2014 /0	I	1	0	1	2	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	02FEB2014 /25	06FEB2014 /-2	I	1	1	1	2	1
	Blood and lymphatic system disorders/ Lymphopenia/ LYMPHOPENIA	27JAN2014 /19	08FEB2014 /0	C	1	0	1	2	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
508-0001/36 /M/A1/Y	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	27JAN2014 /19	08FEB2014 /0	C	1	1	1	2	3
	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	27JAN2014 /19	08FEB2014 /0	I	1	1	1	2	3
	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ PAIN-CHEST WALL	12JAN2014 /4	Unknown/NA	I	6	0	1	5[It May Relate To The Radioactive Particles Implantatio nMetastasis Tumor Of Right Lung.]	1
508-0003/49 /F/A1/Y	Gastrointestinal disorders/ Ascites/ ASCITES	01APR2014 /15	Unknown/NA	C	6	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
508-0003/49 /F/A1/Y	Gastrointestinal disorders/ Abdominal pain/ BELLYACHE	17MAR2014 /0	Unknown/NA	C	6	1	1	4	3
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	01APR2014 /15	Unknown/NA	C	6	1	1	5[It Is Related To Her Tumor Metastasis]	2
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Neoplasm progression/ TUMOR PROGRESSION	15APR2014 /29	15APR2014 /7	C	4	0	2	4[Tumor Progression .]	5
	Investigations/ Blood bilirubin increased/ TBIL INCREASE	08APR2014 /22	Unknown/NA	C	6	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
508-0003/49 /F/A1/Y	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOPENIA	08APR2014 /22	Unknown/NA	C	6	0	1	3	2
	General disorders and administration site conditions/ Asthenia/ FEEBLE	05APR2014 /19	Unknown/NA	C	6	0	1	3	2
	General disorders and administration site conditions/ Oedema/ EDEMA	05APR2014 /19	Unknown/NA	C	6	1	1	3	1
	Investigations/ Blood bilirubin increased/ TBIL INCREASE	25MAR2014 /8	08APR2014 /0	C	2	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
508-0003/49 /F/A1/Y	Investigations/ Blood lactate dehydrogenase increased/ LDH INCREASE	25MAR2014 /8	Unknown/NA	C	6	0	1	3	2
	Investigations/ Gamma-glutamyltransferase increased/ GGT INCREASE	25MAR2014 /8	Unknown/NA	C	6	0	1	3	3
	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	25MAR2014 /8	Unknown/NA	C	6	0	1	3	3
	Investigations/ Aspartate aminotransferase increased/ AST INCREASE	25MAR2014 /8	Unknown/NA	C	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
508-0003/49 /F/A1/Y	Gastrointestinal disorders/ Faecaloma/ COPROSTASIS	26APR2014 /40	Unknown/NA	C	6	1	1	5 [CD]	1
	Gastrointestinal disorders/ Vomiting/ EMESIS	17MAR2014 /0	Unknown/NA	I	6	0	1	3	1
	Gastrointestinal disorders/ Dry mouth/ XEROSTOMIA	17MAR2014 /0	Unknown/NA	C	6	0	1	3	1
509-0001/45 /M/A1/Y	Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIA	07MAY2014 /7	14MAY2014 /-62	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
509-0001/45 /M/A1/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	15JUN2014 /46	18JUN2014 /-27	C	1	0	1	3	1
	General disorders and administration site conditions/ Mass/ RIGHT THIGH MASS	10JUN2014 /41	Unknown/NA	C	6	0	1	4	1
	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	02JUL2014 /63	Unknown/NA	C	6	0	1	3	1
	Investigations/ Aspartate aminotransferase increased/ AST RISE	15JUL2014 /76	Unknown/NA	C	6	0	1	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
509-0001/45 /M/A1/Y	Investigations/ Aspartate aminotransferase increased/ AST RISE	02JUL2014 /63	Unknown/NA	C	6	0	1	3	2
	Gastrointestinal disorders/ Hyperchlorhydria/ HYPERACIDITY	01JUL2014 /62	06JUL2014 /-9	C	1	1	1	3	2
	Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDEMIA	02JUL2014 /63	Unknown/NA	C	6	0	1	3	1
	General disorders and administration site conditions/ Disease progression/ DISEASE PROGRESSION	06AUG2014 /98	06AUG2014 /22	C	4	0	1	5 [PD]	5

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
509-0001/45 /M/A1/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	12JUL2014 /73	14JUL2014 /-1	C	1	1	1	3	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	07MAY2014 /7	05JUN2014 /-40	C	1	0	1	3	2
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	01JUL2014 /62	06JUL2014 /-9	C	1	1	1	3	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	26JUN2014 /57	27JUN2014 /-18	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
509-0001/45 /M/A1/Y	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	05JUN2014 /36	Unknown/NA	C	6	0	1	3	3
	Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDAEMIA	21MAY2014 /21	05JUN2014 /-40	C	1	0	1	3	1
	Nervous system disorders/ Hypoaesthesia/ LIMB NUMBNESS	29MAY2014 /29	Unknown/NA	C	6	0	1	3	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	05JUN2014 /36	06JUN2014 /-39	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
509-0001/45 /M/A1/Y	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT PAIN	03JUN2014 /34	Unknown/NA	C	6	1	1	3	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	03JUN2014 /34	03JUN2014 /-42	C	1	1	1	3	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	25MAY2014 /25	26MAY2014 /-50	C	1	1	1	3	1
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	14MAY2014 /14	16MAY2014 /-60	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
509-0001/45 /M/A1/Y	Musculoskeletal and connective tissue disorders/ Arthralgia/ KNEE-JOINT PAIN	06MAY2014 /6	Unknown/NA	C	6	1	1	3	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENTION	09MAY2014 /9	16MAY2014 /-60	C	1	1	1	3	1
509-0002/51 /M/A1/N	Infections and infestations/ Biliary tract infection/ NOS BILIARY TRACT INFECTION	04JUN2014 /9	Unknown/NA	C	5	0	1	4 [CD]	1
	Investigations/ Aspartate aminotransferase increased/ AST RISE	04JUN2014 /9	11JUN2014 /0	C	1	0	1	4 [PD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
509-0002/51 /M/A1/N	Investigations/ Alanine aminotransferase increased/ ALT RISE	04JUN2014 /9	11JUN2014 /0	C	1	0	1	4 [PD]	1
510-0002/50 /M/A1/Y	Gastrointestinal disorders/ Vomiting/ EMESIS	21JUL2014 /59	22JUL2014 /6	I	1	1	1	4	1
	Investigations/ Blood bilirubin increased/ TOTAL BILIRUBIN INCREASE	28MAY2014 /5	21JUL2014 /5	C	2	3	3 /11JUN2014 /18JUN2014	4	3
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Neoplasm malignant/ MALIGNANT TUMOR	13AUG2014 /82	13AUG2014 /28	C	4	0	1	4 [PD]	5

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
510-0002/50 /M/A1/Y	Investigations/ Blood bilirubin increased/ TOTAL BILIRUBIN EXORBITANT	21JUL2014 /59	13AUG2014 /28	C	1	3	2	4 [CD]	4
	Gastrointestinal disorders/ Flatulence/ FLATULENCE	21JUL2014 /59	13AUG2014 /28	I	1	0	1	4	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	22JUL2014 /60	23JUL2014 /7	I	1	1	1	4	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	12JUL2014 /50	22JUL2014 /6	I	1	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
510-0002/50 /M/A1/Y	Gastrointestinal disorders/ Abdominal pain upper/ UPPER ABDOMINAL PAIN	12JUL2014 /50	13AUG2014 /28	I	1	1	1	4	2
	Hepatobiliary disorders/ Jaundice cholestatic/ OBSTRUCTIVE JAUNDICE	06JUN2014 /14	13AUG2014 /28	C	1	3	3 /11JUN2014 /18JUN2014	4	3
	Gastrointestinal disorders/ Abdominal pain upper/ UPPER ABDOMINAL PAIN	14JUN2014 /22	14JUN2014 /-32	I	1	1	1	4	2
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHY SKIN	27MAY2014 /4	13AUG2014 /28	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
510-0002/50 /M/A1/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	24JUL2014 /62	24JUL2014 /8	I	2	0	1	4	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	23JUL2014 /61	23JUL2014 /7	I	2	1	1	4	2
511-0001/35 /M/A1/N	Investigations/ Platelet count decreased/ PLT DECREASE	08MAR2014 /46	11MAR2014 /14	C	1	1	1	5[Related To Cpt-11 And Xeloda]	1
	Investigations/ Neutrophil count decreased/ NEUTROPHILS ABSOLUTE VALUE DECREASES	11MAR2014 /49	28MAR2014 /31	C	1	0	1	5[Related To Cpt-11 And Xeloda]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
511-0001/35 /M/A1/N	Investigations/ Neutrophil count decreased/ NEUTROPHILS ABSOLUTE VALUE DECREASES	08MAR2014 /46	11MAR2014 /14	C	1	0	1	5[Related To Cpt-11 And Xeloda]	3
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELLS DECREASE	08MAR2014 /46	28MAR2014 /31	C	1	0	1	5[Related To Cpt-11 And Xeloda]	2
511-0002/49 /M/A1/Y	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	05SEP2014 /178	10SEP2014 /22	C	1	0	1	5[Associate d With Liver Interventio nal Treatment]	1
	General disorders and administration site conditions/ Asthenia/ WEAK	10SEP2014 /183	15SEP2014 /27	C	1	0	1	5[Associate d With Liver Interventio nal Treatment]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
511-0002/49 /M/A1/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	10SEP2014 /183	15SEP2014 /27	C	1	1	1	5[Related To Infection]	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	10SEP2014 /183	15SEP2014 /27	C	1	0	1	5[PD]	1
	Hepatobiliary disorders/ Hepatic pain/ HEPATALGIA	06SEP2014 /179	15SEP2014 /27	C	1	0	1	5[PD]	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	05SEP2014 /178	07SEP2014 /19	C	1	0	1	5[PD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
511-0002/49 /M/A1/Y	Investigations/ Platelet count decreased/ PLT DECREASE	24JUN2014 /105	15SEP2014 /27	C	1	0	1	3	1
	Investigations/ Neutrophil count decreased/ NEUTROPHILS ABSOLUTE VALUE DECREASE	19AUG2014 /161	10SEP2014 /22	C	1	0	1	5	2
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELLS DECRERSE	05AUG2014 /147	10SEP2014 /22	C	1	0	1	4	2
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELLS DECRERSE	22JUL2014 /133	05AUG2014 /-14	C	1	0	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
511-0002/49 /M/A1/Y	Investigations/ Neutrophil count decreased/ NEUTROPHILS ABSOLUTE VALUE DECREASE	24JUN2014 /105	05AUG2014 /-14	I	1	0	1	3	3
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELLS DECRERSE	24JUN2014 /105	22JUL2014 /-28	I	2	0	1	3	2
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELLS DECREASE	10JUN2014 /91	24JUN2014 /-56	I	2	0	1	3	1
	Investigations/ Neutrophil count decreased/ NEUTROPHILS ABSOLUTE VALUE DECREASE	13MAY2014 /63	10JUN2014 /-70	I	1	0	1	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
511-0002/49 /M/A1/Y	Investigations/ Neutrophil count decreased/ NEUTROPHILS ABSOLUTE VALUE DECREASE	29APR2014 /49	13MAY2014 /-98	I	2	0	1	3	2
	Investigations/ Neutrophil count decreased/ NEUTROPHILS ABSOLUTE VALUE DECREASE	15APR2014 /35	29APR2014 /-112	C	2	0	1	3	3
	Investigations/ Platelet count decreased/ PLT DECREASE	01APR2014 /21	10JUN2014 /-70	C	1	0	1	3	1
	Investigations/ Neutrophil count decreased/ NEUTROPHILS ABSOLUTE VALUE DECREASE	01APR2014 /21	15APR2014 /-126	C	2	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
511-0002/49 /M/Al/Y	Investigations/ White blood cell count decreased/ WHITE BLOOD CELLS DECREASE	01APR2014 /21	10JUN2014 /-70	C	2	0	1	3	2
512-0001/59 /M/Al/N	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Brain cancer metastatic/ BRAIN METASTATIC TUMOR	04SEP2014 /184	04SEP2014 /72	C	4	0	1	5[PD]	5
	Infections and infestations/ Lobar pneumonia/ LEFT LOWER LOBE PNEUMONIA	09JUL2014 /127	Unknown/NA	C	2	3	1	5[Disease Related]	3
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Brain cancer metastatic/ BRAIN METASTATIC TUMOR	24JUN2014 /112	04SEP2014 /72	C	1	3	2	5[PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
513-0001/28 /M/A1/Y	Gastrointestinal disorders/ Mouth haemorrhage/ ORAL CAVITY INTERNAL HEMORRHAGE	26APR2014 /15	21JUN2014 /33	C	4	3	1	4 [PD]	3
513-0004/46 /M/A1/Y	Eye disorders/ Scleral pigmentation/ SCLERA STAINED YELLOW	18JUL2014 /30	26JUL2014 /18	C	1	1	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	15JUL2014 /27	26JUL2014 /18	C	1	1	1	5	2
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	18JUL2014 /30	26JUL2014 /18	C	1	3	1	5 [PD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
513-0004/46 /M/A1/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	16JUL2014 /28	23JUL2014 /15	I	1	3	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ DOUBLE LEG EDEMA	15JUL2014 /27	26JUL2014 /18	C	1	1	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANAEMIA	15JUL2014 /27	26JUL2014 /18	C	1	1	1	5	2
	Gastrointestinal disorders/ Gastrointestinal haemorrhage/ GASTROINTESTINAL HEMORRHAGE	13JUL2014 /25	26JUL2014 /18	I	4	1	2	3	5

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
513-0005/61 /M/A1/N	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENTION	09JAN2015 /70	14JAN2015 /0	C	1	1	1	4	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	07JAN2015 /68	08JAN2015 /-6	I	1	1	1	4	2
	Infections and infestations/ Nasopharyngitis/ COLD	26DEC2014 /56	29DEC2014 /-16	I	1	1	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	25DEC2014 /55	25DEC2014 /-20	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
513-0005/61 /M/A1/N	Infections and infestations/ Nasopharyngitis/ COLD	19DEC2014 /49	20DEC2014 /-25	I	1	1	1	5	2
	Investigations/ Aspartate aminotransferase increased/ ELEVATED SAPARTATE TRANSAMINASE	04DEC2014 /34	Unknown/NA	C	6	1	1	4	3
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	11JAN2015 /72	01MAR2015 /46	C	1	3	1	4 [PD]	3
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	18NOV2014 /18	02DEC2014 /-43	I	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
513-0005/61 /M/A1/N	Gastrointestinal disorders/ Abdominal pain upper/ STOMACH PAIN	12NOV2014 /12	13NOV2014 /-62	I	1	0	1	4	1
515-0001/64 /M/A1/Y	Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEG PAIN	01APR2014* /40	17JUL2014 /71	C	1	1	1	5	2
	Nervous system disorders/ Memory impairment/ MEMORY IMPAIRMENT	29APR2014 /68	17JUL2014 /71	C	1	0	1	5	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	29APR2014 /68	23MAY2014 /16	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
515-0001/64 /M/A1/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	29APR2014 /68	23MAY2014 /16	I	1	1	1	5	2
	Eye disorders/ Vision blurred/ BLURRED VISION	15APR2014 /54	17JUL2014 /71	I	1	0	1	5	1
	Nervous system disorders/ Headache/ HEADACHE	15APR2014 /54	17JUL2014 /71	C	1	1	1	5	2
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to central nervous system/ HCC BRAIN METASTASIS	09MAY2014 /78	17JUL2014 /71	C	1	0	2	5 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
515-0003/69 /M/A1/N	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to lung/ HCC PULMONARY METASTASIS	11AUG2014 /90	Unknown/NA	C	5	1	1	5 [PD]	3
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	18JUN2014 /36	Unknown/NA	C	2	1	1	5 [PD]	2
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	09JUN2014 /27	04JUL2014 /-25	C	1	1	3 /16JUN2014 /11JUL2014	2	2
	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	09JUN2014 /27	04JUL2014 /-25	C	1	1	3 /16JUN2014 /11JUL2014	2	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
515-0004/52 /M/A1/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ HCC PROGRESSION	17SEP2014 /113	19SEP2014 /4	C	1	3	1	5 [PD]	4
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to central nervous system/ HCC PROGRESSION	17SEP2014 /113	19SEP2014 /4	C	4	3	1	5 [PD]	5
515-0006/47 /M/A1/Y	Gastrointestinal disorders/ Vomiting/ VOMIT	19AUG2014 /14	Unknown/NA	I	2	0	1	4	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	19AUG2014 /14	Unknown/NA	I	2	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
515-0006/47 /M/A1/Y	Psychiatric disorders/ Insomnia/ INSOMNIA	30AUG2014 /25	05SEP2014 /-45	C	1	1	3 /30AUG2014 /09SEP2014	4 [Unknown]	2
515-0008/60 /M/A1/N	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to lung/ HCC PULMONARY METASTASIS	02MAR2015 /95	Unknown/NA	C	5	1	1	5 [PD]	3
516-0001/45 /M/A1/Y	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DCRESED	10OCT2014 /63	07NOV2014 /-70	C	1	0	1	3	1
	Investigations/ Neutrophil count decreased/ NEUTROPHIL COUNT DECREASED	26SEP2014 /49	10OCT2014 /-98	C	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
516-0001/45 /M/A1/Y	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	26SEP2014 /49	10OCT2014 /-98	C	2	0	1	3	2
	Investigations/ Neutrophil count decreased/ NEUTROPHIL COUNT DECREASED	29AUG2014 /21	12SEP2014 /-126	C	2	1	1	3	3
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	29AUG2014 /21	12SEP2014 /-126	C	2	1	1	3	2
517-0001/42 /M/A1/N	Gastrointestinal disorders/ Oesophageal varices haemorrhage/ ESOPHAGEAL VARICES HEMORRHAGE	16FEB2014 /55	22FEB2014 /33	I	1	0	1	5 [CD]	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0001/42 /M/A1/N	General disorders and administration site conditions/ Injection site pain/ THE INJECTION SITE OF LEFT UPPER ARM MUSCLE PAIN	23JAN2014 /31	02MAR2014 /41	C	5	0	1	3	2
	Musculoskeletal and connective tissue disorders/ Muscular weakness/ THE LEFT HAND MUSCLE WEAKNESS	22JAN2014 /30	02MAR2014 /41	C	5	0	1	4 [PD]	2
	Investigations/ Body temperature increased/ ELEVATED BODY TEMPERATURE	13JAN2014 /21	02MAR2014 /41	C	5	0	1	3	1
	Nervous system disorders/ Hypoaesthesia/ LEFT HAND NUMBNESS	15JAN2014 /23	02MAR2014 /41	C	5	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0001/42 /M/A1/N	General disorders and administration site conditions/ Injection site reaction/ THE INJECTION SITES OF DOUBLE ARM UPPER LIMB MUSCLE WEAKNESS	15JAN2014 /23	23JAN2014 /3	C	5	0	1	3	1
	Nervous system disorders/ Hypoaesthesia/ THE NUMBNESS OF THE RIGHT LOWER LIMBS	08JAN2014 /16	02MAR2014 /41	C	5	0	1	5 [PD]	2
517-0002/43 /M/A1/N	Infections and infestations/ Lyme disease/ LYM REDUCE	08JUL2014 /104	Unknown/NA	C	5	0	1	3	1
	Investigations/ Bilirubin conjugated increased/ DBIL RISE	25JUN2014 /91	08JUL2014 /-57	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0002/43 /M/A1/N	Investigations/ Lymphocyte count decreased/ LYMPHOCYTE COUNT DECREASED	25JUN2014 /91	08JUL2014 /-57	C	1	0	1	3	2
	Investigations/ Blood fibrinogen increased/ FIBRINOGEN INCREEASED	25JUN2014 /91	05AUG2014 /-29	C	1	0	1	3	1
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	25JUN2014 /91	08JUL2014 /-57	C	1	0	1	3	1
	Investigations/ International normalised ratio increased/ INR INCREASED	10JUN2014 /76	08JUL2014 /-57	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0002/43 /M/A1/N	Investigations/ Prothrombin time prolonged/ PROTHROMBIN TIME EXTENDED	10JUN2014 /76	08JUL2014 /-57	C	1	0	1	3	1
	Investigations/ Blood phosphorus decreased/ SERUM INORGANIC PHOSPHORUS DECREASED	10JUN2014 /76	20AUG2014 /-14	C	1	0	1	3	2
	Investigations/ Blood phosphorus decreased/ SERUM INORGANIC PHOSPHORUS DECREASED	27MAY2014 /62	10JUN2014 /-85	C	2	0	1	3	3
	Investigations/ Lymphocyte count decreased/ THE LYMPHOCYTE ABSOLUTE VALUE DECREASES	27MAY2014 /62	25JUN2014 /-70	C	5	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0002/43 /M/A1/N	Investigations/ White blood cell count decreased/ THE DECREASE OF WHITE BLOOD CELL	13MAY2014 /48	27MAY2014 /-99	C	1	1	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	30MAR2014 /4	30MAR2014 /-157	I	5	0	1	3	1
	Investigations/ Neutrophil count decreased/ ABSOLUTE NEUTROPHIL COUNT DECREASED	29APR2014 /34	06MAY2014 /-120	C	1	1	1	3	2
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	29APR2014 /34	06MAY2014 /-120	C	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0002/43 /M/A1/N	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	15APR2014 /20	29APR2014 /-127	C	5	1	1	3	1
517-0006/67 /F/A1/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ HCC PROGRESSION	04MAY2015 /257	11MAY2015 /19	I	1	2	2	5 [PD]	2
	Investigations/ White blood cell count decreased/ THE WBC REDUCE	22APR2015 /245	Unknown/NA	C	5	1	1	3	2
	Investigations/ White blood cell count decreased/ THE WBC REDUCE	08APR2015 /231	22APR2015 /0	C	5	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0006/67 /F/A1/Y	Investigations/ Platelet count decreased/ THE PLT REDUCE	04MAR2015 /196	Unknown/NA	C	5	1	1	3	2
	Investigations/ Platelet count decreased/ THE PLT REDUCED	25FEB2015 /189	04MAR2015 /-49	C	5	1	1	3	1
	Investigations/ Neutrophil count decreased/ ANC REDUCE	04FEB2015 /168	11FEB2015 /-70	C	1	0	1	3	1
	Investigations/ Platelet count decreased/ THE PLT REDUCE	04FEB2015 /168	25FEB2015 /-56	C	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0006/67 /F/A1/Y	Investigations/ Platelet count decreased/ THE PLT REDUCE	28JAN2015 /161	04FEB2015 /-77	C	5	1	1	3	1
	Investigations/ White blood cell count decreased/ THE WBC REDUCE	28JAN2015 /161	08APR2015 /-14	C	1	1	1	3	2
	Investigations/ White blood cell count decreased/ THE WBC REDUCE	21JAN2015 /154	28JAN2015 /-84	C	5	1	1	3	1
	Investigations/ White blood cell count decreased/ THE WBC REDUCE	14JAN2015 /147	21JAN2015 /-91	C	2	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0006/67 /F/A1/Y	Investigations/ White blood cell count decreased/ THE WBC REDUCE	30DEC2014 /132	07JAN2015 /-105	C	1	1	1	3	1
	Investigations/ Platelet count decreased/ THE PLT REDUCE	24DEC2014 /126	28JAN2015 /-84	C	2	1	1	3	2
	Investigations/ White blood cell count decreased/ WBC REDUCED	17DEC2014 /119	24DEC2014 /-119	C	1	1	1	3	1
	Investigations/ Platelet count decreased/ THE PLT REDUCE	10DEC2014 /112	24DEC2014 /-119	C	5	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0006/67 /F/A1/Y	Investigations/ White blood cell count decreased/ WBC REDUCED	10DEC2014 /112	17DEC2014 /-126	C	1	1	1	3	2
	Investigations/ White blood cell count decreased/ WBC REDUCED	26NOV2014 /98	10DEC2014 /-133	C	5	1	1	3	1
	Investigations/ Neutrophil count decreased/ ANC REDUCE	19NOV2014 /91	26NOV2014 /-147	C	1	1	1	3	1
	Investigations/ Neutrophil count decreased/ ANC REDUCE	12NOV2014 /84	19NOV2014 /-154	C	2	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0006/67 /F/A1/Y	Investigations/ Bilirubin conjugated increased/ DBIL RISE	05NOV2014 /77	19NOV2014 /-154	C	1	0	1	3	1
	Investigations/ Platelet count decreased/ PLT REDUCE	22OCT2014 /63	10DEC2014 /-133	C	1	1	1	3	2
	Investigations/ Platelet count decreased/ PLT REDUCE	08OCT2014 /49	22OCT2014 /-182	C	5	0	1	3	1
	Investigations/ Haemoglobin decreased/ HB REDUCE	30SEP2014 /41	08OCT2014 /-196	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0006/67 /F/A1/Y	Investigations/ Platelet count decreased/ PLT REDUCE	30SEP2014 /41	08OCT2014 /-196	C	1	1	1	3	2
	Investigations/ Platelet count decreased/ PLT REDUCE	24SEP2014 /35	30SEP2014 /-204	C	5	0	1	3	1
	Investigations/ Neutrophil count decreased/ ANC REDUCE	10SEP2014 /21	05NOV2014 /-168	C	1	1	1	3	2
	Investigations/ White blood cell count decreased/ WBC REDUCE	10SEP2014 /21	26NOV2014 /-147	C	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0006/67 /F/A1/Y	Investigations/ Platelet count decreased/ PLT REDUCE	10SEP2014 /21	24SEP2014 /-210	C	1	1	1	3	2
	Investigations/ Bilirubin conjugated increased/ DIRECT BILIRUBIN RISING	27AUG2014 /7	10SEP2014 /-224	C	1	0	1	3	1
	Investigations/ Blood bilirubin increased/ TOTAL BILIRUBIN RISING	27AUG2014 /7	10SEP2014 /-224	C	1	0	1	3	1
	Investigations/ Platelet count decreased/ THE PLT ECREASE	27AUG2014 /7	10SEP2014 /-224	C	5	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0007/66 /M/A1/N	Investigations/ Blood alkaline phosphatase increased/ ALP RISING	12SEP2014 /23	15NOV2014 /64	C	5	0	1	3	2
	Investigations/ White blood cell count increased/ WBC RISING	12SEP2014 /23	15NOV2014 /64	C	5	0	1	3	2
	Investigations/ Blood calcium increased/ CALCIUM RISE	27AUG2014 /7	12SEP2014 /0	C	1	0	1	3	1
	Investigations/ Gamma-glutamyltransferase increased/ GGT RISE	27AUG2014 /7	15NOV2014 /64	C	5	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0007/66 /M/A1/N	Investigations/ Lymphocyte count decreased/ LYMPHOCYTES ABSOLUTE VALUE DESCEND	27AUG2014 /7	12SEP2014 /0	C	1	0	1	3	2
	Investigations/ White blood cell count decreased/ WBC DESCEND	27AUG2014 /7	12SEP2014 /0	C	5	0	1	3	1
	Investigations/ Platelet count decreased/ PLT DESCEND	27AUG2014 /7	12SEP2014 /0	C	1	1	1	3	2
517-0008/59 /M/A1/N	Investigations/ Bilirubin conjugated increased/ DBIL RISE	12SEP2014 /21	22OCT2014 /33	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: ADI-PEG 20

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0008/59 /M/A1/N	Investigations/ Platelet count decreased/ PLT REDUCE	12SEP2014 /21	22OCT2014 /33	C	1	0	1	3	2
	Investigations/ Lymphocyte count decreased/ ABSOLUTE VALUE OF LYMPHOCYTES REDUCING	29AUG2014 /7	12SEP2014 /-7	C	1	0	1	3	3
517-0009/23 /M/A1/Y	Investigations/ Aspartate aminotransferase increased/ AST RISE	05NOV2014 /49	07JAN2015 /35	C	1	1	1	3	1
	Investigations/ Alanine aminotransferase increased/ ALT RISE	05NOV2014 /49	19NOV2014 /-14	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0002/70 /M/OTH/N	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Cancer pain/ ABDOMINAL CANCER PAIN	18OCT2011 /81	Unknown/NA	C	5	0	1	5	1
	Investigations/ Blood testosterone decreased/ LOW TESTOSTERONE	01SEP2011* /34	Unknown/NA	C	5	1	1	5	1
	Endocrine disorders/ Hypothyroidism/ HYPOTHYROIDISM	14SEP2011 /47	Unknown/NA	C	6	1	1	5	1
	Renal and urinary disorders/ Dysuria/ DYSURIA	13AUG2011 /15	26AUG2011 /-46	C	1	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0002/70 /M/OTH/N	Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIA	19AUG2011 /21	02SEP2011 /-39	C	1	1	1	4	3
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	13AUG2011 /15	02SEP2011 /-39	C	1	1	1	3	1
	General disorders and administration site conditions/ Mucosal inflammation/ MUCOSITIS	05AUG2011 /7	05AUG2011 /-67	C	1	0	1	4	1
	Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	29JUL2011 /0	29JUL2011 /-74	I	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0002/70 /M/OTH/N	Metabolism and nutrition disorders/ Hypoglycaemia/ HYPOGLYCEMIA	29SEP2011 /62	04OCT2011 /-7	C	1	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ PULMONARY - SHORTNESS OF BREATH	26AUG2011 /28	04OCT2011 /-7	I	1	0	1	4	1
	Renal and urinary disorders/ Nocturia/ NOCTURIA	13AUG2011 /15	26AUG2011 /-46	C	1	0	1	4	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	21SEP2011 /54	10OCT2011 /-1	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0002/70 /M/OTH/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	12OCT2011 /75	Unknown/NA	C	5	0	1	3	1
101-0004/78 /F/A2/N	Musculoskeletal and connective tissue disorders/ Arthralgia/ PAIN-KNEE	10APR2012 /249	Unknown/NA	C	6	1	1	5	1
	Renal and urinary disorders/ Urinary incontinence/ URINARY INCONTINENCE	21SEP2012 /413	28SEP2012 /7	I	1	0	1	5	1
	Psychiatric disorders/ Confusional state/ CONFUSION	27JUL2012 /357	03AUG2012 /-49	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0004/78 /F/A2/N	Metabolism and nutrition disorders/ Hypoglycaemia/ HYPOGLYCEMIA	13JAN2012 /161	13JAN2012 /-252	C	1	0	1	5	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	13AUG2011 /8	Unknown/NA	C	6	0	1	3	1
	Renal and urinary disorders/ Urinary incontinence/ URINARY INCONTINENCE	27JUL2012 /357	03AUG2012 /-49	I	2	0	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	07SEP2011 /33	09SEP2011 /-378	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0004/78 /F/A2/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	27JUL2012 /357	03AUG2012 /-49	I	1	0	1	3	2
101-0014/61 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea exertional/ DYSPNEA ON EXERTION	17FEB2012 /42	Unknown/NA	I	6	0	1	3	1
	Metabolism and nutrition disorders/ Cachexia/ CACHEXIA	02MAY2012 /117	11MAY2012 /28	C	1	0	1	3	2
	Nervous system disorders/ Spinal cord compression/ HIGH-GRADE SPINAL CORD COMPRESSION	02MAY2012 /117	Unknown/NA	C	6	2	2	5 [PD]	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0014/61 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Cough/ DRY COUGH	14FEB2012 /39	16MAR2012 /-28	C	1	0	1	3	1
	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	23MAR2012 /77	06APR2012 /-7	C	1	1	1	5	2
	Gastrointestinal disorders/ Dry mouth/ DRY MOUTH	03FEB2012 /28	10FEB2012 /-63	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Hiccups/ HICCUPS	03FEB2012 /28	10FEB2012 /-63	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0015/65 /M/A4/N	Eye disorders/ Lacrimation increased/ TEARING OF EYES	18JAN2012 /8	30JAN2012 /-50	C	1	0	1	5	1
101-0017/60 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	29FEB2012 /8	27MAR2012 /-35	I	1	0	1	3	1
101-0020/86 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	21AUG2012 /161	28AUG2012 /7	I	1	0	1	4	1
	Infections and infestations/ Bronchitis/ BRONCHITIS	15MAY2012 /63	05JUN2012 /-77	I	1	0	3 /15MAY2012 /05JUN2012	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0020/86 /M/W2/N	General disorders and administration site conditions/ Oedema/ 2+ BILATERAL PITTING LOWER EXTREMITY EDEMA	21AUG2012 /161	27AUG2012 /6	C	1	1	1	4	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	27MAR2012 /14	07AUG2012 /-14	I	1	0	1	2	1
	General disorders and administration site conditions/ Oedema peripheral/ 2+ BILATERAL PITTING LOWER EXTREMITY EDEMA WHICH IS SYMMETRIC	03APR2012 /21	17APR2012 /-126	C	1	0	1	3	2
101-0027/72 /M/W2/N	Infections and infestations/ Bacteraemia/ INFECTION (BACTEREMIA)	15JUN2012 /24	11AUG2012 /64	I	4	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0027/72 /M/W2/N	Investigations/ Cardiac murmur/ SYSTOLIC MURMUR	15JUN2012 /24	16JUN2012 /8	C	1	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	24MAY2012 /2	28MAY2012 /-11	I	1	1	3 /24MAY2012 /07JUN2012	5[CD]	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	22MAY2012 /0	Unknown/NA	C	6	0	1	5	1
101-0031/69 /F/W2/N	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	04SEP2012 /46	Unknown/NA	C	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0031/69 /F/W2/N	Infections and infestations/ Urinary tract infection/ UTI	21SEP2012 /63	25SEP2012 /0	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	21SEP2012 /63	21SEP2012 /-4	C	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	21AUG2012 /32	21AUG2012 /-35	C	1	0	1	1	1
101-0034/44 /M/OTH/Y	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN (INCREASED)	16OCT2012 /35	02NOV2012 /10	C	1	0	3 /02NOV2012 /Unknown	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0034/44 /M/OTH/Y	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIGHT SHOULDER PAIN	16OCT2012 /35	02NOV2012 /10	I	1	0	1	4	2
	Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	02NOV2012 /52	06NOV2012 /14	I	1	0	1	4	2
101-0035/37 /M/A6/Y	Musculoskeletal and connective tissue disorders/ Back pain/ ACUTE WORSENING BACK PAIN	23OCT2012 /39	01NOV2012 /21	C	3	3	1	5[PD]	3
	Nervous system disorders/ Hypoaesthesia/ ARM NUMBNESS	15NOV2012 /62	Unknown/NA	C	6	1	3 /19OCT2012 /Unknown	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0035/37 /M/A6/Y	Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING BACK PAIN	21SEP2012 /7	19OCT2012 /8	C	1	1	3 /21SEP2012 /11OCT2012	5[CD]	3
	Infections and infestations/ Rash pustular/ PAPULOPUSTULAR RASH ON UPPER BACK FROM STEROIDS	22SEP2012 /8	26SEP2012 /-15	C	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Pleuritic pain/ PLEURITIC PAIN	12NOV2012 /59	21NOV2012 /41	C	3	1	1	5[PD]	3
	Respiratory, thoracic and mediastinal disorders/ Haemothorax/ PLEURAL HEMORRHAGE	19OCT2012 /35	Unknown/NA	C	6	3	3 /19OCT2012 /Unknown	5[PD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0035/37 /M/A6/Y	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	21SEP2012 /7	02OCT2012 /-9	C	1	2	3 /21SEP2012 /11OCT2012	5[Clinical Progression ]	3
	Psychiatric disorders/ Insomnia/ INSOMNIA	25SEP2012 /11	Unknown/NA	C	6	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Mediastinal haemorrhage/ MEDIASTINAL HEMORRHAGE	21SEP2012 /7	24SEP2012 /-17	C	1	3	3 /21SEP2012 /11OCT2012	5[Clinical Progression ]	3
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	19OCT2012 /35	Unknown/NA	C	6	2	3 /19OCT2012 /Unknown	5[PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0043/69 /M/W1/N	Gastrointestinal disorders/ Ascites/ ASCITES	19NOV2013 /28	20NOV2013 /-27	C	1	2	1	5	1
	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINEMIA	31DEC2013 /70	Unknown/NA	C	6	0	2	3	3
	Gastrointestinal disorders/ Ascites/ WORSENING ASCITES	31DEC2013 /70	07JAN2014 /21	C	1	2	1	5	2
	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINEMIA	23DEC2013 /62	31DEC2013 /14	C	3	0	3 /23DEC2013 /Unknown	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0051/70 /F/W2/N	Psychiatric disorders/ Confusional state/ CONFUSION	18FEB2014 /22	03MAR2014 /0	I	1	0	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	17FEB2014 /21	03MAR2014 /0	C	1	0	1	3	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	18FEB2014 /22	24FEB2014 /-7	I	1	0	1	4	1
	Nervous system disorders/ Dizziness/ DIZZINESS	10FEB2014 /14	03MAR2014 /0	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0051/70 /F/W2/N	Immune system disorders/ Drug hypersensitivity/ ALLERGY TO MORPHINE	17MAR2014 /49	Unknown/NA	C	6	0	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	21MAR2014 /53	21MAR2014 /18	C	1	1	1	5	1
	Infections and infestations/ Fungal skin infection/ FUNGAL RASH (GROIN)	19MAR2014 /51	22MAR2014 /19	C	1	1	1	5	2
	Injury, poisoning and procedural complications/ Fall/ FALL	04MAR2014 /36	04MAR2014 /1	I	3	2	3 /10MAR2014 /17MAR2014	5[PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0051/70 /F/W2/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	17FEB2014 /21	10MAR2014 /7	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Wheezing/ ANTERIOR WHEEZING	13MAR2014 /45	17MAR2014 /14	C	1	1	1	5	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	18MAR2014 /50	Unknown/NA	I	6	0	1	5	2
	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	13MAR2014 /45	21MAR2014 /18	C	1	1	1	4 [PD]	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
101-0051/70 /F/W2/N	Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIAS	03MAR2014 /35	03MAR2014 /0	C	1	1	1	5	2
	Psychiatric disorders/ Anxiety/ ANXIETY	18MAR2014 /50	19MAR2014 /16	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Rales/ BILATERAL RALES	13MAR2014 /45	17MAR2014 /14	C	1	1	1	5	1
102-0006/66 /M/BL/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	12FEB2014 /63	Unknown/NA	I	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
102-0006/66 /M/BL/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	29JAN2014 /49	Unknown/NA	I	6	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Neck pain/ PAIN (NECK)	23JAN2014 /43	Unknown/NA	I	6	1	1	5	1
	General disorders and administration site conditions/ Injection site pain/ INJECTION SITE REACTION (STINGING)	17DEC2013 /6	17DEC2013 /-64	I	1	0	1	1	1
	Investigations/ Blood glucose increased/ GLUCOSE (HIGH)	12FEB2014 /63	Unknown/NA	C	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
102-0006/66 /M/BL/N	Gastrointestinal disorders/ Abdominal pain/ PAIN (ABDOMINAL)	19FEB2014 /70	Unknown/NA	I	6	1	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea exertional/ DYSPNEA ON EXERTION	29JAN2014 /49	Unknown/NA	I	6	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	29JAN2014 /49	Unknown/NA	I	6	0	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	19FEB2014 /70	Unknown/NA	I	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
102-0006/66 /M/BL/N	Respiratory, thoracic and mediastinal disorders/ Epistaxis/ EPISTAXIS (NOSEBLEED)	29JAN2014 /49	Unknown/NA	I	6	0	1	4	1
102-0007/61 /M/W2/N	Musculoskeletal and connective tissue disorders/ Muscular weakness/ MUSCLE WEAKNESS, GENERALIZED	03MAY2014 /121	19MAY2014 /25	C	1	0	1	4	2
	General disorders and administration site conditions/ Injection site pain/ INTERMITTENT WEEKLY INJECTION SITE REACTION - BURNING	16JAN2014 /14	24APR2014 /0	I	1	0	1	1	1
	Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCULOSKELETAL - OTHER (SPASM)	23JAN2014 /21	19MAY2014 /25	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
102-0007/61 /M/W2/N	Hepatobiliary disorders/ Jaundice/ JAUNDICE	10APR2014 /98	10APR2014 /-14	I	1	0	1	4	1
	Skin and subcutaneous tissue disorders/ Dry skin/ DRY SKIN	30APR2014 /118	30APR2014 /6	I	1	1	1	4	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA	01FEB2014 /30	07FEB2014 /-76	I	1	0	1	4	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	06MAR2014 /63	06MAR2014 /-49	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
102-0007/61 /M/W2/N	Metabolism and nutrition disorders/ Cachexia/ CACHEXIA	10APR2014 /98	10APR2014 /-14	I	1	0	1	4	1
	Hepatobiliary disorders/ Jaundice/ JAUNDICE	01MAY2014 /119	19MAY2014 /25	C	1	0	1	5	2
	Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	01FEB2014 /30	07FEB2014 /-76	I	1	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ PAIN - OTHER (THROAT; ODYNOPHAGIA)	01MAY2014 /119	19MAY2014 /25	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
102-0007/61 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	16JAN2014 /14	19MAY2014 /25	C	1	0	1	4	3
	General disorders and administration site conditions/ Pain/ PAIN	23JAN2014 /21	19MAY2014 /25	C	1	1	1	4	3
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	23JAN2014 /21	19MAY2014 /25	C	1	1	1	4	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	13FEB2014 /42	20FEB2014 /-63	I	1	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
102-0007/61 /M/W2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	23JAN2014 /21	19MAY2014 /25	C	1	1	1	4	1
	Nervous system disorders/ Syncope/ SYNCOPE	04MAY2014 /122	04MAY2014 /10	I	1	0	1	4	3
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	30APR2014 /118	19MAY2014 /25	C	1	1	3 /30APR2014 /Unknown	5[Likely From Infection]	3
	Skin and subcutaneous tissue disorders/ Night sweats/ SWEATING (NIGHTSWEATS)	13JAN2014 /11	07FEB2014 /-76	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
102-0007/61 /M/W2/N	Infections and infestations/ Respiratory tract infection/ INFECTION (RESPIRATORY)	09JAN2014 /7	23JAN2014 /-91	I	1	1	1	4	2
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA: LIMB (BILATERAL FEET)	01APR2014 /89	19MAY2014 /25	C	1	1	1	4	1
	Gastrointestinal disorders/ Abdominal distension/ DISTENSION/BLOATING	13FEB2014 /42	19MAY2014 /25	C	1	1	1	4	2
103-0002/74 /M/W2/N	Musculoskeletal and connective tissue disorders/ Muscle spasms/ CRAMPS (LEGS)	14APR2013 /123	24APR2013 /-21	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
103-0002/74 /M/W2/N	General disorders and administration site conditions/ Chest pain/ CHEST SORENESS/BURNING	18MAR2013 /96	19MAR2013 /-57	I	1	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	03JUN2013 /173	25JUN2013 /41	I	1	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	21DEC2012 /9	26DEC2012 /-140	I	1	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ HEMOPTYSIS	03JUN2013 /173	18JUN2013 /34	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
103-0002/74 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Wheezing/ WHEEZING (LUNGS)	13MAY2013 /152	Unknown/NA	C	6	1	1	4	1
	General disorders and administration site conditions/ Early satiety/ EARLY SATIETY	20FEB2013 /70	Unknown/NA	I	6	0	1	3	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	21DEC2012 /9	26DEC2012 /-140	C	1	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	18MAR2013 /96	01SEP2013 /109	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
103-0002/74 /M/W2/N	Musculoskeletal and connective tissue disorders/ Arthralgia/ WOSENING GENERAL ARTHRALGIAS	07JAN2013 /26	Unknown/NA	I	6	1	1	3	2
	Respiratory, thoracic and mediastinal disorders/ Pulmonary congestion/ CHEST CONGESTION	03JUN2013 /173	25JUN2013 /41	C	1	0	1	4	1
	General disorders and administration site conditions/ Chest pain/ CHEST SORENESS/BURNING	25MAR2013 /103	29MAR2013 /-47	I	1	0	1	4	1
	General disorders and administration site conditions/ Facial pain/ LEFT SIDE FACIAL PAIN	30DEC2012 /18	06FEB2013 /-98	I	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
103-0002/74 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ BLOOD IN SPUTUM	19MAR2013 /97	Unknown/NA	I	6	0	1	4	1
	Infections and infestations/ Lung infection/ INFECTION (LUNG)	13MAY2013 /152	Unknown/NA	C	6	1	1	4	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENTION	20FEB2013 /70	Unknown/NA	I	6	0	1	4	1
	General disorders and administration site conditions/ Oedema peripheral/ TRACE TO 1+ EDEMA BILATERAL EXTREMITIES	16JAN2013 /35	06FEB2013 /-98	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
103-0002/74 /M/W2/N	Ear and labyrinth disorders/ Vertigo/ VERTIGO	30DEC2012 /18	06FEB2013 /-98	I	1	1	1	4	2
103-0006/57 /M/W2/N	Gastrointestinal disorders/ Tongue blistering/ 2 WHITE BLISTERS ON THE RIGHT TONGUE	25NOV2014 /5	04DEC2014 /-54	C	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Flank pain/ RIGHT FLANK PAIN	11DEC2014 /21	16DEC2014 /-42	C	1	0	1	5	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	14DEC2014 /24	20JAN2015 /-7	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
103-0006/57 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	02DEC2014 /12	11DEC2014 /-47	C	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	02DEC2014 /12	11DEC2014 /-47	C	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	02DEC2014 /12	11DEC2014 /-47	C	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Sinus congestion/ SINUS CONGESTION	06JAN2015 /47	20JAN2015 /-7	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
103-0006/57 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	06JAN2015 /47	20JAN2015 /-7	I	1	0	1	5	1
104-0002/80 /M/W2/N	Nervous system disorders/ Dizziness/ LIGHTHEADED	03AUG2012 /88	06AUG2012 /-154	I	1	0	1	4	1
	Gastrointestinal disorders/ Flatulence/ INCREASED GAS PRODUCTION	27AUG2012 /112	04SEP2012 /-125	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	26JUL2012 /80	Unknown/NA	C	6	0	3 /31JUL2012 /06AUG2012	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
104-0002/80 /M/W2/N	Nervous system disorders/ Dizziness/ DIZZINESS	06AUG2012 /91	13AUG2012 /-147	I	1	0	1	4	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	21MAY2012 /14	29MAY2012 /-223	I	1	0	1	4	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	20AUG2012 /105	10SEP2012 /-119	I	1	0	1	4	2
	Gastrointestinal disorders/ Dry mouth/ DRY MOUTH	12JUN2012 /36	Unknown/NA	I	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
104-0002/80 /M/W2/N	General disorders and administration site conditions/ Pain/ BODY ACHES	20AUG2012 /105	27AUG2012 /-133	C	1	0	1	5	1
104-0007/89 /M/A1/N	Injury, poisoning and procedural complications/ Skin abrasion/ RT FOREARM WITH ABRASION	07OCT2014 /426	21OCT2014 /-251	I	1	0	1	5	1
	Injury, poisoning and procedural complications/ Fall/ FALL	02MAY2015 /633	02MAY2015 /-58	C	1	0	1	5	1
	Injury, poisoning and procedural complications/ Skin abrasion/ FOREHEAD ABRASION	02MAY2015 /633	04MAY2015 /-56	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
104-0007/89 /M/A1/N	Renal and urinary disorders/ Stress urinary incontinence/ URINARY STRESS INCONTINENCE	07AUG2013 /0	Unknown/NA	C	6	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ EIPGASTRIC PAIN	13JAN2014 /159	22JAN2014 /-523	I	1	1	1	4	1
	Metabolism and nutrition disorders/ Decreased appetite/ SLIGHT DECREASE IN APPETITE	13JAN2014 /159	22JAN2014 /-523	I	1	0	1	4	1
	Injury, poisoning and procedural complications/ Laceration/ LEFT ELBOW LACERATION	30JAN2014 /176	05FEB2014 /-509	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
105-0003/57 /M/W2/N	Infections and infestations/ Incision site infection/ CHEST WALL INCISION INFECTION	18NOV2013 /12	27DEC2013 /-277	C	1	3	1	4 [CD]	3
	General disorders and administration site conditions/ Injection site pain/ TENDERNESS AT INJECTION SITES	06NOV2013 /0	09NOV2013 /-325	C	1	0	1	1	1
	General disorders and administration site conditions/ Oedema/ TRACE EDEMA	25JUL2014 /261	01AUG2014 /-60	C	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT ABDOMINAL PAIN	15JAN2014 /70	Unknown/NA	I	6	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
105-0003/57 /M/W2/N	General disorders and administration site conditions/ Oedema/ TRACE EDEMA	24JAN2014 /79	31JAN2014 /-242	C	1	0	1	5	1
	Nervous system disorders/ Hepatic encephalopathy/ INCREASED HEPATIC ENCEPHALOPATHY	25JUL2014 /261	Unknown/NA	I	6	1	1	5	2
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	11DEC2013 /35	Unknown/NA	C	6	0	1	3	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	24JUN2014 /230	Unknown/NA	C	6	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
105-0003/57 /M/W2/N	Psychiatric disorders/ Depression/ EXACERBATION OF DEPRESSION	31JAN2014 /86	27FEB2014 /-215	C	1	1	1	4	1
	Nervous system disorders/ Dizziness/ INTERMITTENT DIZZINESS	10JAN2014 /65	Unknown/NA	I	6	0	1	5	1
	Gastrointestinal disorders/ Nausea/ INTERMITTANT NAUSEA	16JAN2014 /71	Unknown/NA	I	6	2	1	3	1
	Reproductive system and breast disorders/ Gynaecomastia/ GYNECOMASTIA	07FEB2014 /93	Unknown/NA	C	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
105-0003/57 /M/W2/N	Gastrointestinal disorders/ Vomiting/ INTERMITTANT VOMITING	16JAN2014 /71	Unknown/NA	I	6	0	1	3	1
	Vascular disorders/ Hypertension/ EXACERBATION OF HYPERTENSION	02JAN2014 /57	Unknown/NA	C	6	1	1	5	1
105-0006/60 /F/BL/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	23FEB2015 /55	Unknown/NA	C	6	0	1	4	1
	Nervous system disorders/ Headache/ HEADACHE	01JAN2015 /2	01JAN2015 /-159	I	1	0	1	4 [Unknown]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
105-0006/60 /F/BL/N	Investigations/ Aspartate aminotransferase increased/ ELEVATED AST - GRADE 3	17MAR2015 /77	Unknown/NA	C	6	0	3 /24MAR2015 /01APR2015	4	3
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	10FEB2015 /42	Unknown/NA	I	6	0	1	4	1
	Investigations/ Aspartate aminotransferase increased/ ELEVATED AST - GRADE 3	19FEB2015 /51	03MAR2015 /-98	C	1	0	1	4	3
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	12MAY2015 /133	12MAY2015 /-28	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
108-0003/85 /M/W2/N	General disorders and administration site conditions/ Injection site pain/ STINGING AT INJECTION SITE	26NOV2012 /7	26NOV2012 /-22	C	1	0	1	1	1
	General disorders and administration site conditions/ Injection site pain/ STINGING AT INJECTION SITE	03DEC2012 /14	03DEC2012 /-15	C	1	0	1	1	1
	Nervous system disorders/ Dysgeusia/ TASTE ALTERATION	03DEC2012 /14	Unknown/NA	C	6	0	1	3	1
	General disorders and administration site conditions/ Injection site pain/ STINGING AT INJECTION SITE	10DEC2012 /21	10DEC2012 /-8	C	1	0	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
108-0003/85 /M/W2/N	Investigations/ International normalised ratio increased/ INR INCREASED	27DEC2012 /38	31DEC2012 /13	C	1	1	1	5 [CM]	3
	General disorders and administration site conditions/ Injection site pain/ STINGING AT INJECTION SITE	19NOV2012 /0	19NOV2012 /-29	C	1	0	1	1	1
	Infections and infestations/ Pneumonia/ PNEUMONIA	18DEC2012 /29	04JAN2013 /17	C	1	1	1	4	2
	General disorders and administration site conditions/ Injection site pain/ STINGING AT INJECTION SITE	18DEC2012 /29	18DEC2012 /0	C	1	0	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0002/63 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LOWER LEG EDEMA	04APR2013 /13	12APR2013 /-133	C	1	0	1	5	1
	Nervous system disorders/ Dysgeusia/ DYSGEUSIA	23MAR2013 /1	02APR2013 /-143	C	1	0	1	3	1
	Eye disorders/ Eye irritation/ EYE IRRITATION	28JUN2013 /98	02AUG2013 /-21	I	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ MYALGIA (BILATERAL LEGS)	27MAY2013 /66	20SEP2013 /28	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0005/64 /F/W2/N	Investigations/ Aspartate aminotransferase increased/ ELEVATED AST	21AUG2013 /21	Unknown/NA	I	6	0	3 /21AUG2013 /28AUG2013	4	4
	General disorders and administration site conditions/ Oedema peripheral/ BLE EDEMA	20AUG2013 /20	Unknown/NA	C	6	1	1	4	2
	Investigations/ Alanine aminotransferase increased/ ELEVATED ALT	21AUG2013 /21	Unknown/NA	I	6	0	3 /21AUG2013 /28AUG2013	4	3
	General disorders and administration site conditions/ Fatigue/ FATIGUE	09AUG2013 /9	Unknown/NA	C	6	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0005/64 /F/W2/N	Renal and urinary disorders/ Acute kidney injury/ WORSENING ACUTE KIDNEY INJURY (DUE TO DECOMPENSATION OF BIVENTRICULAR HEART FAILURE)	11SEP2013 /42	08OCT2013 /34	C	4	1	2	5 [CD]	4
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	20AUG2013 /20	Unknown/NA	I	6	1	1	4	1
	Cardiac disorders/ Cardiac failure/ HEART FAILURE	11SEP2013 /42	Unknown/NA	C	6	3	1	5 [CD]	4
109-0012/21 /F/W2/N	Nervous system disorders/ Headache/ HEADACHES	13NOV2014 /49	Unknown/NA	I	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0012/21 /F/W2/N	Investigations/ Blood alkaline phosphatase increased/ ELEVATED ALK PHOS	11NOV2014 /47	Unknown/NA	C	6	0	1	3	3
	Investigations/ Aspartate aminotransferase increased/ ELEVATED AST	11NOV2014 /47	Unknown/NA	C	6	0	1	3	3
	Nervous system disorders/ Dysgeusia/ DYSGEUSIA	25SEP2014 /0	Unknown/NA	I	6	0	1	1	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ PAIN (OPPOSITE SIDE OF BUTTOCKS THAN INJECTION SITE)	25SEP2014 /0	Unknown/NA	I	6	0	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0012/21 /F/W2/N	Investigations/ Alanine aminotransferase increased/ ELEVATED ALT	11NOV2014 /47	Unknown/NA	C	6	0	1	3	3
	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINEMIA	11NOV2014 /47	Unknown/NA	C	6	0	2	3	2
109-0014/50 /F/W2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	02FEB2015 /7	04FEB2015 /-28	C	1	0	1	5	1
	Infections and infestations/ Bronchitis/ BRONCHIAL INFECTION	01FEB2015 /6	Unknown/NA	C	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0014/50 /F/W2/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	01FEB2015 /6	Unknown/NA	C	6	1	1	5	2
	Infections and infestations/ Cellulitis/ BILATERAL LOWER EXTREMITY CELLULITIS	15FEB2015 /20	Unknown/NA	I	6	1	1	5	2
	Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	11MAR2015 /44	19MAR2015 /15	C	1	1	1	5[CD]	3
	General disorders and administration site conditions/ Fatigue/ FATIGUE	24FEB2015 /29	Unknown/NA	I	6	2	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0014/50 /F/W2/N	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT PAIN	03FEB2015 /8	Unknown/NA	I	6	0	1	5	1
	Psychiatric disorders/ Delirium/ DELIRIUM	18MAR2015 /51	Unknown/NA	C	6	1	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ PERIPHERAL EDEMA	26JAN2015 /0	Unknown/NA	C	6	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING BACK PAIN	08FEB2015 /13	11FEB2015 /-21	C	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
109-0014/50 /F/W2/N	Metabolism and nutrition disorders/ Hypercalcaemia/ HYPERCALCEMIA	11MAR2015 /44	13MAR2015 /9	C	1	1	1	5 [PD]	4
111-0003/37 /M/A1/Y	Nervous system disorders/ Headache/ HEADACHE	09FEB2013 /32	Unknown/NA	C	6	1	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	12MAR2013 /63	Unknown/NA	C	6	2	1	4	1
	Gastrointestinal disorders/ Abdominal pain/ PAIN IN ABDOMEN	26FEB2013 /49	Unknown/NA	C	6	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0003/37 /M/A1/Y	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	26FEB2013 /49	28FEB2013 /7	C	1	0	1	4	1
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	07MAR2013 /58	Unknown/NA	C	6	1	1	4	2
	Respiratory, thoracic and mediastinal disorders/ Respiratory failure/ RESPIRATORY FAILURE DUE TO CANCER	19MAR2013 /70	19MAR2013 /26	C	4	3	1	5 [PD]	5
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ LEFT SHOULDR PAIN	27FEB2013 /50	28FEB2013 /7	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0003/37 /M/A1/Y	Nervous system disorders/ Headache/ HEADACHE	20JAN2013 /12	21JAN2013 /-31	C	1	1	1	4	3
	Nervous system disorders/ Headache/ HEADACHE	24JAN2013 /16	25JAN2013 /-27	C	1	1	1	4	3
	Nervous system disorders/ Balance disorder/ LOSS OF BALANCE	23FEB2013 /46	24FEB2013 /3	C	1	0	1	4	1
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING HAND	27FEB2013 /50	28FEB2013 /7	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0003/37 /M/A1/Y	Nervous system disorders/ Balance disorder/ LOSS OF BALANCE	02FEB2013 /25	06FEB2013 /-15	C	1	0	1	4	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ PAIN IN LEFT SHOULDER	30JAN2013 /22	01FEB2013 /-20	C	1	3	1	4	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	15FEB2013 /38	28FEB2013 /7	C	1	1	1	3	2
	Investigations/ Alanine aminotransferase increased/ ELEVATED ALT	28FEB2013 /51	07MAR2013 /14	C	1	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0003/37 /M/A1/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	30JAN2013 /22	22FEB2013 /1	C	1	1	1	4	1
	Nervous system disorders/ Headache/ FULLNESS IN HEAD (HEADACHE)	30JAN2013 /22	01FEB2013 /-20	C	1	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	01MAR2013 /52	Unknown/NA	C	6	0	1	4	2
	Hepatobiliary disorders/ Portal vein thrombosis/ PORTAL VEIN THROMBOSIS	13MAR2013 /64	Unknown/NA	C	6	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0003/37 /M/A1/Y	Eye disorders/ Diplopia/ DOUBLE VISION	24JAN2013 /16	25JAN2013 /-27	C	1	1	1	4	3
	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	02FEB2013 /25	17FEB2013 /-4	C	1	3	1	4	1
	Investigations/ Aspartate aminotransferase increased/ ELEVATED AST (338)	28FEB2013 /51	Unknown/NA	C	6	0	1	4	3
	Musculoskeletal and connective tissue disorders/ Muscular weakness/ WEAKNESS IN BOTH LEGS	04MAR2013 /55	Unknown/NA	C	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0003/37 /M/A1/Y	Eye disorders/ Diplopia/ DOUBLE VISION	02FEB2013 /25	06FEB2013 /-15	C	1	1	1	4	3
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	04MAR2013 /55	05MAR2013 /12	I	1	0	1	3	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	19FEB2013 /42	Unknown/NA	C	6	1	1	4	1
	Gastrointestinal disorders/ Dyspepsia/ DYSPEPSIA	31JAN2013 /23	07MAR2013 /14	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0003/37 /M/A1/Y	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	07MAR2013 /58	Unknown/NA	C	6	0	1	4	3
	Nervous system disorders/ Dysgeusia/ BITTER TASTE IN THE MOUTH (DYSGEUSIA)	21FEB2013 /44	Unknown/NA	C	6	0	1	4	1
	Renal and urinary disorders/ Chromaturia/ URINE DISCOLORATION	04MAR2013 /55	Unknown/NA	C	6	0	1	4	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	08JAN2013 /0	17JAN2013 /-35	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0003/37 /M/A1/Y	General disorders and administration site conditions/ Fatigue/ FATIGUE	01MAR2013 /52	Unknown/NA	C	6	0	1	4	3
	Gastrointestinal disorders/ Abdominal distension/ BLOATING	26FEB2013 /49	Unknown/NA	C	6	1	1	4	1
	Psychiatric disorders/ Depression/ DEPRESSION	08JAN2013 /0	Unknown/NA	C	6	1	1	5	2
	Psychiatric disorders/ Anxiety/ ANXIETY	07FEB2013 /30	Unknown/NA	C	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
111-0003/37 /M/A1/Y	Skin and subcutaneous tissue disorders/ Rash/ RASH (FACE)	26FEB2013 /49	Unknown/NA	C	6	1	1	4	1
	Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	12MAR2013 /63	16MAR2013 /23	C	1	2	1	4	3
	Gastrointestinal disorders/ Diarrhoea/ SEVERE DIARRHEA	05MAR2013 /56	16MAR2013 /23	C	1	1	1	4[Etiology Likely Viral Vs Bacterial Colitis.]	4
112-0010/56 /F/W2/N	Nervous system disorders/ Dizziness/ DIZZINESS	31JAN2014 /56	07FEB2014 /-14	I	1	0	1	4[CM]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0010/56 /F/W2/N	Psychiatric disorders/ Hallucination/ OCCASINAL HALLUCINATIONS	11DEC2013 /5	Unknown/NA	I	6	0	1	5 [CM]	1
	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LOWER EXTREMITY EDEMA (BLEE)	03JAN2014 /28	Unknown/NA	C	6	1	1	5 [CD]	2
	Investigations/ Blood alkaline phosphatase increased/ ALK PHOS (ELEVATED)	24JAN2014 /49	26MAR2014 /33	C	1	0	1	4 [CD]	2
	Infections and infestations/ Urinary tract infection/ UTI	04FEB2014 /60	14FEB2014 /-7	C	1	1	1	4 [CD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0010/56 /F/W2/N	Investigations/ International normalised ratio increased/ INR (HIGH)	21FEB2014 /77	Unknown/NA	C	6	0	1	5 [CD]	1
	Gastrointestinal disorders/ Stomatitis/ MOUTH SORES	19JAN2014 /44	31JAN2014 /-21	C	1	1	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	19JAN2014 /44	Unknown/NA	I	6	1	1	3	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	09FEB2014 /65	Unknown/NA	I	6	1	1	4 [CD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0010/56 /F/W2/N	Investigations/ Lymphocyte count decreased/ LYMPHOCYTE (LOW)	07FEB2014 /63	Unknown/NA	C	6	0	1	3	1
	Investigations/ Blood albumin decreased/ ALBUMIN (LOW)	21FEB2014 /77	Unknown/NA	C	6	0	1	4 [CD]	2
	Investigations/ Aspartate aminotransferase increased/ AST HIGH	10JAN2014 /35	Unknown/NA	C	6	0	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH (DECREASED AIR EXCHANGE)	26MAR2014 /110	Unknown/NA	I	6	0	1	5 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0010/56 /F/W2/N	General disorders and administration site conditions/ Face oedema/ FACIAL EDEMA	17DEC2013 /11	26MAR2014 /33	C	1	0	1	4[Part Of Underlying Issues (Med History)]	1
	Investigations/ Alanine aminotransferase increased/ ALT HIGH	07DEC2013 /1	Unknown/NA	C	6	0	1	3	1
	Investigations/ Blood albumin decreased/ ALBUMIN (LOW)	24JAN2014 /49	21FEB2014 /0	C	1	0	1	4[CD]	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	09DEC2013 /3	20DEC2013 /-63	I	1	1	1	4[CM]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0010/56 /F/W2/N	General disorders and administration site conditions/ Injection site discomfort/ DISCOMFORT AT INJECTION SITE	06DEC2013 /0	Unknown/NA	I	6	0	1	1	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	28DEC2013 /22	Unknown/NA	I	6	1	1	5 [CM]	1
	Nervous system disorders/ Sedation/ SEDATION	07DEC2013 /1	Unknown/NA	I	6	0	1	4 [CM]	1
	Investigations/ Haemoglobin decreased/ HGB (LOW)	07FEB2014 /63	Unknown/NA	C	6	0	1	4 [CD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0010/56 /F/W2/N	Investigations/ Blood glucose increased/ GLUCOSE (HIGH)	13DEC2013 /7	27DEC2013 /-56	C	1	0	1	4[Dietary]	1
	Investigations/ Blood alkaline phosphatase increased/ ALK PHOS ELEVATED	13DEC2013 /7	24JAN2014 /-28	C	1	0	1	3	3
	General disorders and administration site conditions/ Fatigue/ FATIGUE	07DEC2013 /1	Unknown/NA	C	6	0	1	4[CD]	1
	Nervous system disorders/ Syncope/ SYNCOPAL EPISODE	31DEC2013 /25	03JAN2014 /-49	I	1	0	1	5[CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0010/56 /F/W2/N	Gastrointestinal disorders/ Vomiting/ VOMITING	15MAR2014 /99	16MAR2014 /23	I	1	3	1	5 [CD]	2
	Nervous system disorders/ Tremor/ INTERMITTENT BILATERAL HAND TREMBLING	12JAN2014 /37	26MAR2014 /33	I	1	0	1	4 [CM]	2
	Vascular disorders/ Hypertension/ HTN (HYPERTENSION)	19JAN2014 /44	Unknown/NA	C	6	1	1	4 [CD]	2
	Investigations/ Blood albumin decreased/ ALBUMIN LOW	13DEC2013 /7	24JAN2014 /-28	C	1	0	1	4 [CD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
112-0010/56 /F/W2/N	Investigations/ Aspartate aminotransferase increased/ AST ELEVATED	13DEC2013 /7	27DEC2013 /-56	C	1	0	1	3	1
	Investigations/ Aspartate aminotransferase increased/ AST HIGH	27DEC2013 /21	10JAN2014 /-42	C	1	0	1	3	2
	Investigations/ Lymphocyte count decreased/ LYMPHOCYTE (LOW)	10JAN2014 /35	07FEB2014 /-14	C	1	0	1	3	2
	Investigations/ Haemoglobin decreased/ HGB LOW	13DEC2013 /7	10JAN2014 /-42	C	1	0	1	4 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0007/74 /M/W2/N	General disorders and administration site conditions/ Fatigue/ SEVERE FATIGUE	05JUL2014 /156	07JUL2014 /18	C	1	0	1	4 [PD]	3
	General disorders and administration site conditions/ Asthenia/ WEAKNESS	05JUL2014 /156	07JUL2014 /18	C	1	0	1	4 [PD]	3
	Skin and subcutaneous tissue disorders/ Nail disorder/ THINNING NAILS	03APR2014 /63	23APR2014 /-57	C	1	0	1	4	1
	Hepatobiliary disorders/ Jaundice/ POSTERIOR PALATE MILD JAUNDICE	20FEB2014 /21	30APR2014 /-50	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0007/74 /M/W2/N	Eye disorders/ Eye irritation/ BURNING OF EYES	09MAR2014 /38	17MAR2014 /-94	I	1	1	1	4	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE THE FOLLOWING DAYS AFTER INJECTIONS	31JAN2014 /1	02FEB2014 /-137	I	1	0	1	3	1
	Skin and subcutaneous tissue disorders/ Scab/ SCAB IN THE NOSE	07MAR2014 /36	14MAR2014 /-97	I	1	1	1	4	1
	Gastrointestinal disorders/ Abdominal hernia/ VENTRAL HERNIA	18APR2014 /78	27JUL2014 /38	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0007/74 /M/W2/N	Investigations/ Heart rate increased/ INCREASED PULSE RATE	05FEB2014 /6	05FEB2014 /-134	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	19MAR2014 /48	27JUL2014 /38	I	1	0	1	4	1
	Gastrointestinal disorders/ Ascites/ ASCITES	13JUN2014 /134	27JUL2014 /38	C	1	2	1	4	1
	Hepatobiliary disorders/ Jaundice/ JAUNDICE-SCLERAL ICTERUS	10JUN2014 /131	27JUL2014 /38	C	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0007/74 /M/W2/N	Injury, poisoning and procedural complications/ Animal bite/ CAT BITE	07JUN2014 /128	19JUN2014 /0	C	1	1	1	5	1
	Cardiac disorders/ Tachycardia/ TACHYCARDIA	05APR2014 /65	05APR2014 /-75	I	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH	03APR2014 /63	27JUL2014 /38	I	1	1	1	4	1
	Eye disorders/ Eye irritation/ BURNING EYES	13FEB2014 /14	25FEB2014 /-114	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0007/74 /M/W2/N	Hepatobiliary disorders/ Jaundice/ POSTERIOR PALATE MILD JAUNDICE	20FEB2014 /21	30APR2014 /-50	C	1	0	1	3	2
	Respiratory, thoracic and mediastinal disorders/ Epistaxis/ NOSE BLEED	07MAR2014 /36	14MAR2014 /-97	I	1	0	1	4	1
113-0015/58 /F/BL/N	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	19DEC2014 /23	06JAN2015 /28	C	1	1	1	4	2
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ BILATERAL SHOULDER PAIN	27NOV2014 /1	19DEC2014 /10	I	3	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
113-0015/58 /F/BL/N	Investigations/ Breath sounds abnormal/ DIMINISHED BS THROUGHOUT LUNG FIELDS	19DEC2014 /23	Unknown/NA	C	6	0	1	4	2
114-0001/25 /F/OTH/Y	General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	02AUG2012 /0	02AUG2012 /-40	C	1	0	1	1	1
	Skin and subcutaneous tissue disorders/ Alopecia/ ALOPECIA	04SEP2012 /33	Unknown/NA	C	6	0	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	08AUG2012 /6	10AUG2012 /-32	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
114-0001/25 /F/OTH/Y	Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING PAIN BACK	21SEP2012 /50	Unknown/NA	C	6	1	1	5	3
	Gastrointestinal disorders/ Toothache/ PAIN - TOOTH	27AUG2012 /25	04SEP2012 /-7	C	1	3	1	5	3
	Gastrointestinal disorders/ Nausea/ NAUSEA	27AUG2012 /25	Unknown/NA	I	6	1	1	3	1
	Nervous system disorders/ Headache/ HEADACHE	28AUG2012 /26	Unknown/NA	I	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
114-0001/25 /F/OTH/Y	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	04SEP2012 /33	Unknown/NA	I	6	0	1	3	1
	Gastrointestinal disorders/ Abdominal pain/ WORSENING PAIN ABDOMEN	21SEP2012 /50	Unknown/NA	C	6	1	1	5	3
	Gastrointestinal disorders/ Rectal haemorrhage/ RECTAL HEMORRHAGE	07AUG2012 /5	07AUG2012 /-35	C	1	0	1	4	1
	Injury, poisoning and procedural complications/ Arthropod bite/ SKIN IRRITATION RELATED TO BUG BITES	04SEP2012 /33	Unknown/NA	C	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
114-0001/25 /F/OTH/Y	Nervous system disorders/ Dizziness/ DIZZINESS	08AUG2012 /6	Unknown/NA	I	6	0	1	3	1
114-0004/54 /F/Al/Y	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPITORY INFECTION	26MAR2013 /48	01APR2013 /5	C	1	0	1	5	1
	Nervous system disorders/ Headache/ HEADACHE	13MAR2013 /35	Unknown/NA	I	6	0	1	3	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	01MAR2013 /23	Unknown/NA	C	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
114-0004/54 /F/A1/Y	Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIA	13FEB2013 /7	Unknown/NA	C	6	0	1	5	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	05MAR2013 /27	05MAR2013 /-22	C	1	0	1	3	2
115-0005/60 /M/W2/N	Gastrointestinal disorders/ Dysphagia/ DYSPHAGIA	15MAR2013 /0	Unknown/NA	I	6	0	1	5	1
115-0006/62 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ LOWER EXTREMITY EDEMA	27JUN2013 /77	Unknown/NA	C	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
115-0006/62 /M/W2/N	Skin and subcutaneous tissue disorders/ Dermal cyst/ BENIGN PILAR CYST	13JUN2013 /63	Unknown/NA	C	6	0	1	5	1
	Psychiatric disorders/ Anxiety/ ANXIETY	06JUN2013 /56	07JUN2013 /-26	C	1	0	1	5	1
	Gastrointestinal disorders/ Ascites/ ASCITES	25JUN2013 /75	Unknown/NA	C	6	1	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ LOWER EXTREMITY EDEMA	16MAY2013 /35	27JUN2013 /-6	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
115-0007/57 /M/W2/N	Gastrointestinal disorders/ Vomiting/ EMESIS	09MAY2013 /20	Unknown/NA	I	6	0	1	5	1
	Gastrointestinal disorders/ Retching/ DRY HEAVES	25APR2013 /6	Unknown/NA	I	6	1	1	5	1
	Skin and subcutaneous tissue disorders/ Night sweats/ NIGHT SWEATS	25APR2013 /6	Unknown/NA	I	6	0	1	4	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	25APR2013 /6	Unknown/NA	I	6	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
121-0003/65 /M/BL/N	Investigations/ Aspartate aminotransferase increased/ ELEVATED AST	02JUL2014 /0	24SEP2014 /35	C	1	0	1	5	1
	General disorders and administration site conditions/ Injection site pain/ PAIN AT INJECTION SITE	30JUL2014 /28	06AUG2014 /-14	C	1	0	1	1	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	09JUL2014 /7	Unknown/NA	C	6	0	1	4	2
201-0002/76 /M/W2/N	Investigations/ Blood phosphorus decreased/ BLOOD PHOSPHORUS DECREASE	26JUL2012 /133	09AUG2012 /-182	C	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0002/76 /M/W2/N	Investigations/ Platelet count decreased/ PLATELETS DECREASE	04OCT2012 /203	15NOV2012 /-84	C	1	0	1	5	2
	Investigations/ Platelet count decreased/ PLATELETS DECREASE	05APR2012 /21	31MAY2012 /-252	C	1	0	1	5	1
	Investigations/ Platelet count decreased/ PLATELETS DECREASE	24JAN2013 /315	02OCT2013 /237	C	1	0	1	5	1
	Investigations/ Blood creatinine increased/ INCREASE CREATININE	28DEC2012 /288	10JAN2013 /-28	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0002/76 /M/W2/N	Investigations/ Platelet count decreased/ PLATELETS DECREASE	31MAY2012 /77	14JUN2012 /-238	C	1	0	1	5	2
	Investigations/ Blood phosphorus decreased/ BLOOD PHOSPHORUS DECREASE	20SEP2012 /189	04OCT2012 /-126	C	1	0	1	3	2
	Investigations/ Platelet count decreased/ PLATELETS DECREASE	20SEP2012 /189	04OCT2012 /-126	C	1	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	01MAY2012 /47	05MAY2012 /-278	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0002/76 /M/W2/N	Investigations/ Blood phosphorus decreased/ BLOOD PHOSPHORUS DECREASE	31MAY2012 /77	28JUN2012 /-224	C	1	0	1	3	2
	Investigations/ Platelet count decreased/ PLATELETS DECREASE	15NOV2012 /245	10JAN2013 /-28	C	1	0	1	5	1
	Investigations/ Platelet count decreased/ PLATELETS DECREASE	28JUN2012 /105	20SEP2012 /-140	C	1	0	1	5	2
	Investigations/ Platelet count decreased/ PLATELETS DECREASE	10JAN2013 /301	24JAN2013 /-14	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0002/76 /M/W2/N	Investigations/ Blood phosphorus decreased/ BLOOD PHOSPHORUS DECREASE	21MAR2012 /6	17MAY2012 /-266	C	1	0	1	3	2
	Investigations/ Platelet count decreased/ PLATELETS DECREASE	14JUN2012 /91	28JUN2012 /-224	C	1	0	1	5	3
	Gastrointestinal disorders/ Ascites/ ASCITES	04JUN2012 /81	26JUL2012 /-196	C	1	1	1	5	2
201-0006/71 /M/W2/N	Investigations/ Platelet count decreased/ PLATELETS DECREASE	08NOV2012 /119	Unknown/NA	C	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0006/71 /M/W2/N	Infections and infestations/ Pneumonia/ PNEUMONIA	14DEC2012 /155	05JAN2013 /18	C	1	1	1	5	2
	Gastrointestinal disorders/ Ascites/ ASCITES	19JUL2012 /7	Unknown/NA	C	6	1	1	5	2
	Investigations/ Platelet count decreased/ PLATELETS DECREASE	27SEP2012 /77	08NOV2012 /-40	C	1	0	1	5	1
	Investigations/ Platelet count decreased/ PLATELETS DECREASE	02AUG2012 /21	30AUG2012 /-110	C	2	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0006/71 /M/W2/N	Investigations/ Platelet count decreased/ PLATELETS DECREASE	30AUG2012 /49	12SEP2012 /-97	C	1	0	1	5	1
	Investigations/ Platelet count decreased/ PLATELET DECREASE	12SEP2012 /62	27SEP2012 /-82	C	2	0	1	5	2
	Investigations/ Creatinine renal clearance decreased/ CREATININE CLEARANCE DECREASE	27SEP2012 /77	Unknown/NA	C	6	0	1	5	1
201-0007/71 /M/W2/N	Investigations/ Aspartate aminotransferase increased/ INCREASE AST	12SEP2012 /48	25OCT2012 /-154	C	2	0	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0007/71 /M/W2/N	Investigations/ Aspartate aminotransferase increased/ INCREASE AST	22NOV2012 /119	06DEC2012 /-112	C	1	0	1	4	1
	Investigations/ Aspartate aminotransferase increased/ INCREASE AST	14MAR2013 /231	Unknown/NA	C	6	0	1	5	1
	Cardiac disorders/ Ventricular arrhythmia/ VENTRICULAR ARRHYTMIA NOS	26JUL2012 /0	26JUL2012 /-245	I	1	0	1	3	1
	Investigations/ Aspartate aminotransferase increased/ INCREASE AST	25OCT2012 /91	22NOV2012 /-126	C	2	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0007/71 /M/W2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	29JAN2013 /187	04FEB2013 /-52	C	1	1	1	5	1
	Investigations/ Aspartate aminotransferase increased/ INCREASE AST	06DEC2012 /133	14MAR2013 /-14	C	1	0	1	4	2
201-0009/65 /M/W2/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	08JAN2014 /202	11JAN2014 /-535	C	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	23JAN2014 /217	23JAN2014 /-523	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0009/65 /M/W2/Y	Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIA	05SEP2013 /77	18SEP2013 /-650	C	1	0	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	26DEC2013 /189	29DEC2013 /-548	C	1	1	1	5	1
	Metabolism and nutrition disorders/ Hypophosphataemia/ HYPOPHOSPHATEMIA	27JUN2013 /7	11JUL2013 /-719	C	1	0	1	3	2
201-0015/49 /M/W2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	19FEB2014 /195	23FEB2014 /-18	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0022/80 /F/W2/N	Investigations/ Neutrophil count decreased/ DECREASE TOTAL ANC	03JUL2014 /49	16JUL2014 /-99	C	1	0	1	5	2
	Investigations/ White blood cell count decreased/ WBC DECREASED	23OCT2014 /161	Unknown/NA	C	6	0	1	5	2
	Investigations/ White blood cell count decreased/ WBC DECREASED	11SEP2014 /119	25SEP2014 /-28	C	1	0	1	5	2
	Investigations/ Neutrophil count decreased/ DECREASE TOTAL ANC	05JUN2014 /21	03JUL2014 /-112	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0022/80 /F/W2/N	Investigations/ White blood cell count decreased/ DECREASE WBC	21MAY2014 /6	16JUL2014 /-99	C	1	0	1	4	2
	Investigations/ Neutrophil count decreased/ TOTAL ANC DECREASED	13AUG2014 /90	28AUG2014 /-56	C	1	0	1	5	1
	Investigations/ Neutrophil count decreased/ DECREASE TOTAL ANC	21MAY2014 /6	05JUN2014 /-140	C	1	0	1	4	2
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	23OCT2014 /161	25NOV2014 /33	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0022/80 /F/W2/N	Investigations/ White blood cell count decreased/ WBC DECREASED	13AUG2014 /90	28AUG2014 /-56	C	1	0	1	5	1
	Investigations/ White blood cell count decreased/ WBC DECREASED	09OCT2014 /147	23OCT2014 /0	C	1	0	1	5	1
	Investigations/ Neutrophil count decreased/ TOTAL ANC DECREASED	11SEP2014 /119	25SEP2014 /-28	C	1	0	1	5	1
	Investigations/ White blood cell count decreased/ WBC DECREASED	31JUL2014 /77	13AUG2014 /-71	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
201-0022/80 /F/W2/N	Investigations/ Neutrophil count decreased/ TOTAL ANC DECREASED	31JUL2014 /77	13AUG2014 /-71	C	1	0	1	5	2
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	09OCT2014 /147	23OCT2014 /0	C	1	0	1	5	1
203-0004/81 /M/W2/N	Renal and urinary disorders/ Nocturia/ NICTURIA	01OCT2012* /185	15NOV2012 /-53	C	1	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	22MAY2012 /53	31MAY2012 /-221	C	3	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0004/81 /M/W2/N	Investigations/ Neutrophil count increased/ HIGHT VALUE OF NEUTROPHILS	11MAY2012 /42	31MAY2012 /-221	C	1	1	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	21APR2012 /22	22APR2012 /-260	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	22MAY2012 /53	31MAY2012 /-221	C	1	0	1	5	1
	Gastrointestinal disorders/ Faeces discoloured/ BLACK STOOLS	25JUN2012 /87	25JUN2012 /-196	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0004/81 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ LEGS EDEMA	11OCT2012 /195	Unknown/NA	C	6	0	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ DECREASED APPETITE	28JUN2012 /90	19JUL2012 /-172	C	1	0	1	5	1
	Gastrointestinal disorders/ Gastric disorder/ GASTROPATHY	03JUL2012 /95	Unknown/NA	C	6	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ ABDOMINAL PAIN ( RIGHT HYPOCONDRIUM AND RIGHT EPIGASTRIC )	06MAY2012 /37	10MAY2012 /-242	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0004/81 /M/W2/N	Blood and lymphatic system disorders/ Leukocytosis/ LEUKOCYTOSIS	11MAY2012 /42	22MAY2012 /-230	C	1	1	1	5	3
	Metabolism and nutrition disorders/ Decreased appetite/ DECREASED APPETITE	06MAY2012 /37	10MAY2012 /-242	C	1	0	1	5	1
	General disorders and administration site conditions/ Gait disturbance/ WALKING DIFFICULTY	11MAY2012 /42	22MAY2012 /-230	C	3	0	1	5	3
	Metabolism and nutrition disorders/ Decreased appetite/ DECREASED APPETITE	21APR2012 /22	22APR2012 /-260	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0004/81 /M/W2/N	Metabolism and nutrition disorders/ Decreased appetite/ DECREASED APPETITE	01SEP2012* /155	Unknown/NA	C	6	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	07MAY2012 /38	21MAY2012 /-231	C	3	0	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	07MAY2012 /38	08MAY2012 /-244	C	1	1	1	5	1
	Investigations/ C-reactive protein increased/ HIGHT VALUE OF PROTEIN C REACTIVE	11MAY2012 /42	31MAY2012 /-221	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0004/81 /M/W2/N	Metabolism and nutrition disorders/ Hyperkalaemia/ IPERKALEMIA	05JUL2012 /97	12JUL2012 /-179	C	1	1	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	01SEP2012* /155	Unknown/NA	C	6	0	1	5	1
203-0006/76 /M/W2/Y	General disorders and administration site conditions/ Oedema peripheral/ LEGS EDEMA	20JUN2012 /70	07JUL2012 /26	C	1		1	5[CD]	3
	Nervous system disorders/ Dysgeusia/ ALTERED SENSE OF TASTE	11APR2012* /0	31MAY2012* /-11	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0006/76 /M/W2/Y	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	02MAY2012 /21	02MAY2012 /-40	C	1	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	26APR2012 /15	Unknown/NA	C	6	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	19APR2012 /8	31MAY2012* /-11	I	1	1	1	2	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	11APR2012* /0	31MAY2012* /-11	C	3	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0006/76 /M/W2/Y	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	26APR2012 /15	31MAY2012* /-11	C	1	1	1	5	1
	Investigations/ Weight decreased/ WEIGHT LOSS	26APR2012 /15	Unknown/NA	C	6	0	1	5	1
	Investigations/ Blood alkaline phosphatase increased/ HIGHT LEVEL OF ALKALINE PHOSPHATASE	19APR2012 /8	07JUL2012 /26	C	1	0	1	5	3
	Blood and lymphatic system disorders/ Leukocytosis/ LEUKOCYTOSIS	26APR2012 /15	25MAY2012 /-17	I	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0006/76 /M/W2/Y	Investigations/ Aspartate aminotransferase increased/ HIGHT LEVEL OF AST	04MAY2012 /23	07JUL2012 /26	C	1	0	1	5	3
	General disorders and administration site conditions/ Oedema peripheral/ LEGS EDEMA	01JUN2012* /51	Unknown/NA	C	6	1	1	5	1
	General disorders and administration site conditions/ Pyrexia/ PERSISTENT FEVER	07MAY2012 /26	10MAY2012 /-32	C	1	1	1	5[CD]	1
	Respiratory, thoracic and mediastinal disorders/ Respiratory disorder/ UPPER AIRWAYS DISEASE	11APR2012* /0	31MAY2012* /-11	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0006/76 /M/W2/Y	General disorders and administration site conditions/ General physical health deterioration/ DETERIORATION OF CLINICAL CONDITION ( GENERAL PHYSICAL HEALTH DETERIORATION )	07JUL2012 /87	07JUL2012 /26	C	4	0	2	5 [PD]	5
	Metabolism and nutrition disorders/ Decreased appetite/ IPORESSIA ( DECREASED APPETITE )	20JUN2012 /70	07JUL2012 /26	C	1		1	5[Hepatocel lular Carcinoma (Iporessia Was Due To Clinical Condition Deteriorati on Thaw Was Probably Related To Cancer Clinical Progression ) ]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
	General disorders and administration site conditions/ Fatigue/ FATIGUE	20JUN2012 /70	07JUL2012 /26	C	1		1	5[Hepatocel lular Carcinoma]	3
203-0007/59 /M/W2/N	Skin and subcutaneous tissue disorders/ Pruritus/ ARMS PRURITUS	04JUN2012 /0	02OCT2012 /74	C	3	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0007/59 /M/W2/N	Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCOLESTEROLEMIA	01AUG2012 /58	07AUG2012 /18	C	3	1	2	1	4
	Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCOLESTEROLEMIA	27JUN2012 /23	05JUL2012 /-15	C	3	0	1	1	2
	Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCOLESTEROLEMIA	06JUL2012 /32	31JUL2012 /11	C	3	0	3 /26JUL2012 /Unknown	1	3
	Gastrointestinal disorders/ Ascites/ ASCITES	08AUG2012 /65	02OCT2012 /74	C	3	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0007/59 /M/W2/N	Psychiatric disorders/ Anxiety/ ANXIETY	01AUG2012 /58	02OCT2012 /74	C	3	1	1	5	1
	Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCOLESTEROLEMIA	08AUG2012 /65	02OCT2012 /74	C	3	1	1	1	3
203-0009/73 /M/W2/N	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	13SEP2012 /0	19SEP2012 /-407	C	1	0	1	5	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	24FEB2013 /164	26FEB2013 /-247	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0009/73 /M/W2/N	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	20SEP2012 /7	26SEP2012 /-400	C	1	0	1	5	1
	Nervous system disorders/ Encephalopathy/ ENCEPHALOPATHY	14OCT2013 /396	20OCT2013 /-11	C	1	0	3 /14OCT2013 /21OCT2013	5	1
	Investigations/ Weight decreased/ WEIGHT LOSS	18SEP2013 /370	Unknown/NA	C	6	0	1	5	1
	Nervous system disorders/ Asterixis/ FLAPPING TREMOR	20NOV2013 /433	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0009/73 /M/W2/N	Gastrointestinal disorders/ Vomiting/ VOMITING	24FEB2013 /164	26FEB2013 /-247	C	1	0	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ LEGS EDEMA	25JAN2013 /134	08MAR2013 /-237	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ DRY COUGH	24DEC2012 /102	Unknown/NA	C	6	1	1	5	1
	Nervous system disorders/ Encephalopathy/ ENCEPHALOPATHY	18JUN2013 /278	24JUN2013 /-129	C	1	1	1	5[Hepatocel lular Carcinoma]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0009/73 /M/W2/N	Nervous system disorders/ Encephalopathy/ ENCEPHALOPATHY	02SEP2013 /354	09SEP2013 /-52	C	1	1	3 /02SEP2013 /12SEP2013	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIRRHEA	01APR2013* /200	31MAY2013* /-153	I	1	0	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ REDUCED APPETITE	18SEP2013 /370	Unknown/NA	C	6	0	1	5	1
	Gastrointestinal disorders/ Gastrointestinal haemorrhage/ GASTRO INTESTINAL BLEEDING	02SEP2013 /354	09SEP2013 /-52	C	1	1	3 /02SEP2013 /12SEP2013	5[CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0009/73 /M/W2/N	Nervous system disorders/ Encephalopathy/ ENCEPHALOPATHY	15JUN2013 /275	17JUN2013 /-136	C	3	0	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	08MAR2013 /176	18MAR2013 /-227	C	1	0	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ LEGS EDEMA	22AUG2013 /343	26SEP2013 /-35	C	1	1	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	13SEP2012* /0	13SEP2012 /-413	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0009/73 /M/W2/N	Musculoskeletal and connective tissue disorders/ Back pain/ LOMBAR PAIN	20DEC2012 /98	Unknown/NA	C	6	0	1	5	1
	Nervous system disorders/ Asterixis/ FLAPPING TREMOR	03OCT2013 /385	31OCT2013 /0	C	1	0	1	5	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	20SEP2012 /7	Unknown/NA	C	6	0	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	01JAN2013* /110	Unknown/NA	I	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0009/73 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ LEGS EDEMA	27SEP2012 /14	25OCT2012 /-371	C	1	0	1	5	1
	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	27SEP2012 /14	Unknown/NA	C	6	0	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	24FEB2013 /164	26FEB2013 /-247	C	1	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	12SEP2013 /364	17SEP2013 /-44	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0009/73 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	20NOV2013 /433	Unknown/NA	C	6	0	1	5	1
	Psychiatric disorders/ Disorientation/ NEUROLOGICAL DISORDERS ( DISORIENTATION )	18JUN2013 /278	24JUN2013 /-129	C	1	1	1	5[Hepatocel lular Carcinoma]	3
203-0010/74 /M/W2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	28JUN2013 /275	29JUN2013 /-482	C	1	1	1	5	1
	General disorders and administration site conditions/ Non-cardiac chest pain/ NON CARDIAC CHEST PAIN	03FEB2014 /495	16FEB2014 /-250	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0010/74 /M/W2/N	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Hepatocellular carcinoma/ HCC METASTASIS RESECTION	03NOV2014 /768	12NOV2014 /19	C	1	0	1	5 [PD]	3
	Renal and urinary disorders/ Dysuria/ BURNING WITH URINATION	28JUN2013 /275	29JUN2013 /-482	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	03FEB2014 /495	24FEB2014 /-242	C	1	1	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	10FEB2014 /502	24FEB2014 /-242	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0010/74 /M/W2/N	Nervous system disorders/ Psychomotor hyperactivity/ PSYCHOMOTOR AGITATION	06NOV2014 /771	07NOV2014 /14	C	1	1	1	5	2
203-0014/73 /M/W2/N	Hepatobiliary disorders/ Portal vein thrombosis/ PORTAL VEIN THROMBOSIS	26FEB2014 /34	Unknown/NA	C	6	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Back pain/ LUMBAR PAIN	07FEB2014 /15	27FEB2014 /-7	C	1	1	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	27JAN2014 /4	27JAN2014 /-38	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0014/73 /M/W2/N	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	30JAN2014 /7	18FEB2014 /-16	C	1	1	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	28FEB2014 /36	01MAR2014 /-5	C	1	0	1	1	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	07FEB2014 /15	18FEB2014 /-16	C	1	0	1	5	1
203-0016/57 /M/W2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	26APR2014 /81	27APR2014 /-95	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0016/57 /M/W2/N	Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN	01APR2014 /56	22SEP2014 /53	C	1	1	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ TORAX PRURITUS	14MAR2014 /38	31MAR2014 /-122	C	1	0	1	5	1
	Gastrointestinal disorders/ Dyspepsia/ DYSPEPSIA	06MAR2014 /30	22SEP2014 /53	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	10JUN2014 /126	22SEP2014 /53	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0016/57 /M/W2/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	31JUL2014 /177	22SEP2014 /53	I	1	0	1	5	1
	Nervous system disorders/ Dizziness/ DIZZINESS	04FEB2014* /0	18FEB2014 /-163	C	1	0	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	18JUL2014 /164	24JUL2014 /-7	I	1	0	1	5	1
	Renal and urinary disorders/ Renal failure/ RENAL FAILURE	05SEP2014 /213	22SEP2014 /53	C	1	0	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0016/57 /M/W2/N	Musculoskeletal and connective tissue disorders/ Bone pain/ BONE PAIN	31JUL2014 /177	22SEP2014 /53	I	1	0	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	18JUL2014 /164	24JUL2014 /-7	I	1	0	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	31JUL2014 /177	22SEP2014 /53	I	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIGHT SHOULDER PAIN	31MAR2014 /55	07APR2014 /-115	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0016/57 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	01APR2014 /56	22SEP2014 /53	C	1	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	05MAR2014 /29	05MAR2014 /-148	C	1	0	1	1	1
	Gastrointestinal disorders/ Dyspepsia/ HEARTBURN	31JUL2014 /177	22SEP2014 /53	I	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ RIGHT SIDE ABDOMINAL PAIN	18FEB2014 /14	26FEB2014 /-155	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0016/57 /M/W2/N	Gastrointestinal disorders/ Ascites/ ASCITES	27MAY2014 /112	22SEP2014 /53	C	1	1	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ LOW APPETITE	18JUL2014 /164	22SEP2014 /53	C	1	0	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	01MAY2014* /86	18JUN2014 /-43	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	01APR2014* /56	19MAY2014 /-73	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0019/68 /M/W2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	01JUN2014* /10	30JUN2014 /0	C	1	0	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ LEGS EDEMA	30JUN2014 /39	Unknown/NA	C	6	1	1	5	1
	Gastrointestinal disorders/ Ascites/ ASCITES	04JUL2014 /43	Unknown/NA	C	6	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Muscle spasms/ LEGS CRAMPS	29MAY2014 /7	06JUN2014 /-24	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
203-0019/68 /M/W2/N	Musculoskeletal and connective tissue disorders/ Arthralgia/ ANKLE JOINT PAIN	01JUN2014* /10	Unknown/NA	C	6	1	1	5	1
204-0003/64 /M/W2/N	Musculoskeletal and connective tissue disorders/ Muscle spasms/ THIGH CRAMPS	16JUL2013 /8	16JUL2013 /-72	I	1	0	1	5	2
	Psychiatric disorders/ Insomnia/ INSOMNIA	01OCT2013* /85	Unknown/NA	C	6	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ PAIN AT SHOULDER JOINT	19AUG2013 /42	26AUG2013 /-31	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
204-0003/64 /M/W2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	06AUG2013 /29	08AUG2013 /-49	I	1	0	1	4	1
	Vascular disorders/ Bleeding varicose vein/ BLEEDING VARICOSE VEINS DUE TO SCRATCHING	15AUG2013 /38	26AUG2013 /-31	I	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ ABDOMINAL PAIN IN RIGHT HYPOCHONDRIAC REGION	16AUG2013 /39	20AUG2013 /-37	C	1	0	1	4	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	16AUG2013 /39	20AUG2013 /-37	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
204-0003/64 /M/W2/N	Gastrointestinal disorders/ Dyspepsia/ DYSPEPSIA	22SEP2013 /76	23SEP2013 /-3	I	1	1	1	3	3
204-0004/76 /F/W2/Y	Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	12DEC2013 /87	28FEB2014 /78	I	1	0	1	5	3
	Infections and infestations/ Oral herpes/ HERPES SIMPLEX LABIALIS LESIONS	17SEP2013 /1	01OCT2013 /-72	C	3	1	1	5	2
	Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	07NOV2013 /52	21NOV2013 /-21	I	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
204-0004/76 /F/W2/Y	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRALGIA	01DEC2013* /76	12DEC2013 /0	I	1	0	1	4	1
	General disorders and administration site conditions/ Asthenia/ ASTHENIA	01DEC2013* /76	30JAN2014 /49	C	1	1	1	4	1
	Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	11OCT2013 /25	07NOV2013 /-35	I	1	1	1	5	3
	Vascular disorders/ Hypertension/ WORSENING HYPERTENSION	28NOV2013 /73	05DEC2013 /-7	I	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0002/71 /M/W2/N	Investigations/ Aspartate aminotransferase increased/ INCREASED AST	30MAR2012 /35	04APR2012 /-34	C	1	2	3 /04APR2012 /13APR2012	3	3
	Investigations/ Alanine aminotransferase increased/ ALT INCREASING	30MAR2012 /35	26APR2012 /-12	C	1	0	1	5	1
	General disorders and administration site conditions/ Asthenia/ ASTHENIA	03MAR2012 /8	Unknown/NA	C	6	0	1	2	1
	Investigations/ Aspartate aminotransferase increased/ AST INCREASING	04APR2012 /40	12APR2012 /-26	C	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0002/71 /M/W2/N	Gastrointestinal disorders/ Abdominal pain upper/ PAIN IN HYPOCONDRIUM	04APR2012 /40	12APR2012 /-26	C	1	3	1	5	2
	Investigations/ Aspartate aminotransferase increased/ AST INCREASING	13APR2012 /49	Unknown/NA	C	6	0	3 /20APR2012 /27APR2012	3	3
	Gastrointestinal disorders/ Abdominal pain upper/ PAIN IN HYPOCONDRIUM	13APR2012 /49	Unknown/NA	C	6	0	1	5	1
	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINEMIA	27APR2012 /63	07MAY2012 /-1	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0002/71 /M/W2/N	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINEMIA	08MAY2012 /74	Unknown/NA	C	6	0	1	5	2
	Nervous system disorders/ Encephalopathy/ ENCEPHALOPATHY	01JUN2012 /98	14JUN2012 /37	C	1	1	1	4	2
	Infections and infestations/ Influenza/ FLU EPISODE	28FEB2012 /4	28FEB2012 /-70	C	1	1	1	5	1
	Investigations/ Alanine aminotransferase increased/ ALT INCREASING	27APR2012 /63	Unknown/NA	C	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0002/71 /M/W2/N	Renal and urinary disorders/ Chromaturia/ HYPERCHROMIC URINE	04MAY2012 /70	Unknown/NA	C	6	0	1	5	1
	Investigations/ Blood cholesterol increased/ CHOLESTEROL INCREASE	08MAY2012 /74	Unknown/NA	C	6	0	1	5	2
	Nervous system disorders/ Encephalopathy/ ENCEPHALOPATHY	28MAY2012 /94	31MAY2012 /23	C	1	1	1	4[PD]	3
	Eye disorders/ Ocular icterus/ SCLERAL ICTERUS	08MAY2012 /74	Unknown/NA	C	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0002/71 /M/W2/N	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Tumour haemorrhage/ BLEEDING FROM INTRAHEPATIC TUMOR LESIONS	10MAY2012 /76	30MAY2012 /22	C	1	0	3 /10MAY2012 /Unknown	5[PD]	3
	General disorders and administration site conditions/ Injection site pain/ PAIN AT SITE OF INJECTION	12MAR2012 /17	23MAR2012 /-46	C	1	0	1	1	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ MUSCULOSKELETAL PAIN	03MAR2012 /8	Unknown/NA	C	6	0	1	2	1
	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	20MAR2012 /25	Unknown/NA	C	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0002/71 /M/W2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	17MAR2012 /22	08MAY2012 /0	I	1	1	1	2	1
	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCRESING	30MAR2012 /35	07MAY2012 /-1	C	1	0	1	5	2
	Investigations/ Blood albumin decreased/ ALBUMIN DECREASE	08MAY2012 /74	Unknown/NA	C	6	0	1	5	1
205-0003/79 /M/W2/N	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL SWELLING	22MAY2012 /56	22MAY2012 /-196	C	1	0	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0003/79 /M/W2/N	Investigations/ Electrocardiogram QT prolonged/ QT PROLONGATION	12JUN2012 /77	Unknown/NA	C	6	0	1	5	1
	Skin and subcutaneous tissue disorders/ Ecchymosis/ THREE 1-CM-LARGE ECCHYMOSES ON LEFT ARM NOT DUE TO ANY TRAUMA	20JUL2012 /115	07AUG2012 /-119	C	1	0	1	3	1
	General disorders and administration site conditions/ Asthenia/ ASTHENIA EPISODE AFTER A LIGHT PHYSICAL EFFORT	22APR2012 /26	22APR2012 /-226	C	1	0	1	4	1
	Investigations/ Electrocardiogram QT prolonged/ QT PROLONGATION	27MAR2012 /0	14MAY2012 /-204	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0003/79 /M/W2/N	Ear and labyrinth disorders/ Tinnitus/ TINNITUS	05APR2012 /9	07APR2012 /-241	C	1	0	1	3	1
	Investigations/ Electrocardiogram QT prolonged/ QT PROLONGATION	15MAY2012 /49	11JUN2012 /-176	C	1	0	1	5	2
	Nervous system disorders/ Dizziness/ DIZZINESS	02APR2012 /6	02APR2012 /-246	C	1	0	1	4	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL SWELLING	09MAY2012 /43	09MAY2012 /-209	C	1	0	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0003/79 /M/W2/N	Cardiac disorders/ Bradycardia/ BRADYCARDIA	27MAR2012 /0	Unknown/NA	C	6	0	1	4	1
	Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	12JUN2012 /77	26JUN2012 /-161	C	1	1	1	3	3
	General disorders and administration site conditions/ Oedema peripheral/ LIGHT LEG EDEMA	30MAY2012 /64	30JUN2012* /-157	C	1	1	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS AT ARMS	10APR2012 /14	17APR2012 /-231	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0003/79 /M/W2/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	07AUG2012 /133	14AUG2012 /-112	C	1	0	1	4	1
	Reproductive system and breast disorders/ Gynaecomastia/ GYNAECOMASTIA	30JUL2012 /125	23OCT2012 /-42	C	1	0	1	4	1
	Vascular disorders/ Hypotension/ HYPOTENSIVE EPISODE	26OCT2012 /213	26OCT2012 /-39	C	1	0	1	4	2
	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	30SEP2012 /187	23OCT2012 /-42	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0003/79 /M/W2/N	Investigations/ Creatinine renal clearance decreased/ CREATININE CLEARANCE DECREASE	30MAR2012 /3	Unknown/NA	C	6	0	1	5	2
205-0005/71 /M/W2/Y	General disorders and administration site conditions/ Asthenia/ ASTHENIA	31MAY2012 /72	27JUN2012 /22	C	1	1	1	3	1
	Gastrointestinal disorders/ Faeces pale/ HYPOCHOLIC STOOLS	10MAY2012 /51	28JUN2012 /23	C	1	0	1	5	2
	General disorders and administration site conditions/ Pyrexia/ EPISODES OF FEVER IN THE EVENING (MAX 37.2°)	20APR2012 /31	03MAY2012 /-33	I	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0005/71 /M/W2/Y	General disorders and administration site conditions/ Injection site pain/ PAIN AT SITE OF INJECTION	04APR2012 /15	06APR2012 /-60	C	1	0	1	1	1
	General disorders and administration site conditions/ Pyrexia/ LIGHT FEVER (37.1°)	12APR2012 /23	12APR2012 /-54	C	1	0	1	3	1
	Renal and urinary disorders/ Chromaturia/ HYPERCHROMIC URINE	03MAY2012 /44	28JUN2012 /23	C	1	0	1	5	2
	Renal and urinary disorders/ Nocturia/ POLYURIA ESPECIALLY AT NIGHT	20APR2012 /31	Unknown/NA	I	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0005/71 /M/W2/Y	Investigations/ Weight decreased/ WEIGHT LOSS	31MAY2012 /72	Unknown/NA	C	6	0	1	3	1
	General disorders and administration site conditions/ Asthenia/ ASTHENIA	05JUL2012 /107	19JUL2012 /44	C	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	28JUN2012 /100	20JUL2012 /45	C	1	1	1	5	1
	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINEMIA	26APR2012 /37	Unknown/NA	C	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0005/71 /M/W2/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostatic adenoma/ PROSTATIC ADENOMA	23MAY2012 /64	Unknown/NA	C	6	1	1	5	1
	Nervous system disorders/ Dizziness/ DIZZINESS	20APR2012 /31	03MAY2012 /-33	I	1	0	1	3	1
	Gastrointestinal disorders/ Ascites/ ASCITES	05JUN2012 /77	15JUN2012 /10	C	1	0	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ PERIMALLEOLAR EDEMA	05JUL2012 /107	20JUL2012 /45	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0005/71 /M/W2/Y	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	28MAY2012 /69	05JUN2012 /0	C	1	1	1	3	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	13JUN2012 /85	20JUL2012 /45	C	1	1	1	5	1
	Investigations/ Blood albumin decreased/ DECREASED ALBUMIN	05JUN2012 /77	06SEP2012 /93	C	1	0	1	3	2
	Gastrointestinal disorders/ Ascites/ ASCITES	05JUL2012 /107	20JUL2012 /45	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0005/71 /M/W2/Y	Reproductive system and breast disorders/ Prostatic disorder/ PROSTATIC CONGESTION	17MAY2012 /58	23MAY2012 /-13	C	1	1	1	5	1
	Infections and infestations/ Escherichia urinary tract infection/ E.COLI URINARY INFECTION	05JUL2012 /107	19SEP2012 /106	C	1	1	1	5	3
	General disorders and administration site conditions/ Injection site pain/ PAIN AT SITE OF INJECTION	20MAR2012 /0	21MAR2012 /-76	C	1	0	1	1	1
	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	05JUN2012 /77	06SEP2012 /93	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0005/71 /M/W2/Y	Investigations/ White blood cell count increased/ HIGH LEVEL OF WBC (11.49 GI/L)	24MAY2012 /65	05JUN2012 /0	C	1	0	1	5	
	General disorders and administration site conditions/ Injection site pain/ PAIN AT SITE OF INJECTION	29MAR2012 /9	30MAR2012 /-67	C	1	0	1	1	1
	Investigations/ Neutrophil count increased/ INCREASED NEUTROPHIL COUNT (8.63) GI/L	24MAY2012 /65	05JUN2012 /0	C	1	0	1	5	
	General disorders and administration site conditions/ Injection site pain/ PAIN AT SITE OF INJECTION	12APR2012 /23	30APR2012* /-36	C	1	0	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0005/71 /M/W2/Y	Metabolism and nutrition disorders/ Decreased appetite/ HYPOREXIA	05JUN2012 /77	20JUL2012 /45	C	1	0	1	3	1
	General disorders and administration site conditions/ Chills/ SHIVERS	12APR2012 /23	12APR2012 /-54	I	1	0	1	3	1
	General disorders and administration site conditions/ Asthenia/ ASTHENIA	28JUN2012 /100	04JUL2012 /29	C	1	1	1	5	2
	General disorders and administration site conditions/ Injection site pain/ PAIN AT SITE OF INJECTION	17MAY2012 /58	31MAY2012 /-5	C	1	0	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0014/70 /M/W2/N	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	28JUN2013 /10	Unknown/NA	C	6	2	1	5	1
	Infections and infestations/ Rhinitis/ CORYZA	31JUL2013 /43	31AUG2013* /29	C	1	0	1	5	1
	General disorders and administration site conditions/ Asthenia/ ASTHENIA	05JUL2013 /17	Unknown/NA	I	6	2	3 /05JUL2013 /18JUL2013	5	1
	Nervous system disorders/ Serotonin syndrome/ SEROTINA FEVER	31JUL2013 /43	31AUG2013* /29	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0014/70 /M/W2/N	Gastrointestinal disorders/ Ascites/ ASCITES	26JUL2013 /38	02AUG2013 /0	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	13AUG2013 /56	31AUG2013* /29	I	1	0	2	5	3
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	02SEP2013 /76	02OCT2013 /61	C	3	2	1	5 [PD]	3
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	14AUG2013 /57	29AUG2013 /27	C	1	2	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0014/70 /M/W2/N	Gastrointestinal disorders/ Ascites/ ASCITES	05JUL2013 /17	18JUL2013 /-15	C	1	3	3 /05JUL2013 /18JUL2013	5	1
	Gastrointestinal disorders/ Abdominal distension/ METEORISM	12JUL2013 /24	18JUL2013 /-15	I	1	0	1	5	1
	Gastrointestinal disorders/ Ascites/ ASCITES	13AUG2013 /56	29AUG2013 /27	C	1	2	1	5[PD]	3
	Infections and infestations/ Pneumonia/ PNEUMONIA	14AUG2013 /57	Unknown/NA	C	6	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0026/61 /F/W2/N	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	16APR2015 /66	28APR2015 /0	C	1	1	1	5	2
	General disorders and administration site conditions/ Non-cardiac chest pain/ NON CARDIAC CHEST PAIN	09FEB2015 /0	10FEB2015 /-77	C	1	0	1	4	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	24MAR2015 /43	31MAR2015 /-28	C	1	1	1	5	1
	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	26MAR2015 /45	Unknown/NA	C	6	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0026/61 /F/W2/N	Cardiac disorders/ Left ventricular dysfunction/ LEFT VENTRICULAR DIASTOLIC ALTERATION	06MAR2015 /25	Unknown/NA	C	6	1	1	4	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	26MAR2015 /45	Unknown/NA	C	6	2	1	5	2
205-0028/73 /F/W2/N	General disorders and administration site conditions/ Asthenia/ ASTHENIA	03FEB2015 /7	Unknown/NA	C	6	0	1	5	1
	Nervous system disorders/ Dysgeusia/ DISGEUSIA	03FEB2015 /7	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
205-0028/73 /F/W2/N	General disorders and administration site conditions/ Performance status decreased/ PERFORMANCE STATUS DETERIORATION	10FEB2015 /14	15FEB2015 /12	C	4	1	2	5 [PD]	3
207-0002/71 /M/W2/N	General disorders and administration site conditions/ Asthenia/ ASTHENIA	07JUN2012 /77	11JUN2012 /0	C	1	0	1	3	1
	Skin and subcutaneous tissue disorders/ Rash/ SMALL RASH NEAR THE LEFT ANKLE	24MAY2012 /63	31MAY2012 /-11	C	1	1	1	2	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	06JUN2012 /76	11JUN2012 /0	C	1	0	3 /07JUN2012 /11JUN2012	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0007/72 /M/W2/N	General disorders and administration site conditions/ Asthenia/ ASTHENIA	17SEP2012 /77	Unknown/NA	C	6	0	1	5[General Conditions]	1
	Metabolism and nutrition disorders/ Metabolic acidosis/ METABOLIC ACIDOSIS	21SEP2012 /81	29SEP2012 /12	C	1	3	1	5[CD]	3
	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINEMIA	23JUL2012 /21	Unknown/NA	C	6	0	1	3	2
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHY HEAD AND ARMS	23JUL2012 /21	Unknown/NA	C	6	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0007/72 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ INFERIOR LEGS EDEMA	23JUL2012 /21	03SEP2012 /-14	C	1	0	1	4	1
	General disorders and administration site conditions/ Oedema peripheral/ LEGS EDEMA	17SEP2012 /77	Unknown/NA	C	6	0	1	4	2
207-0012/67 /M/W2/Y	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	31DEC2013 /285	07JAN2014 /-17	C	1	0	1	5[CD]	2
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	11APR2013 /21	17APR2013 /-282	C	1	0	1	4[General Status]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0012/67 /M/W2/Y	General disorders and administration site conditions/ Asthenia/ ASTHENIA	01OCT2013* /194	31OCT2013 /-85	C	1	0	1	2	1
	Nervous system disorders/ Headache/ HEADACHE	01FEB2014* /317	14FEB2014 /21	C	1	0	1	5	1
	Psychiatric disorders/ Confusional state/ MENTAL CONFUSION	01FEB2014* /317	14FEB2014 /21	C	1	0	1	5	1
	General disorders and administration site conditions/ Asthenia/ ASTHENIA	24JAN2014 /309	Unknown/NA	C	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0012/67 /M/W2/Y	General disorders and administration site conditions/ General physical health deterioration/ WORSENING GENERAL CONDITION	31JAN2014 /316	Unknown/NA	C	6	0	1	5	2
	Gastrointestinal disorders/ Ascites/ ASCITES	30AUG2013 /162	11OCT2013 /-105	C	1	1	1	4[Hcc Related Suspected]	2
	General disorders and administration site conditions/ Oedema/ AEDEMA	27DEC2013 /281	Unknown/NA	C	6	3	1	5	1
	Gastrointestinal disorders/ Ascites/ ASCITIS	29NOV2013 /253	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0012/67 /M/W2/Y	General disorders and administration site conditions/ Asthenia/ ASTENIA	27DEC2013 /281	10JAN2014 /-14	C	1	0	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ LOWER LIMBS EDEMA	27DEC2013 /281	Unknown/NA	C	6	0	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	24JAN2014 /309	31JAN2014 /7	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Electrolyte imbalance/ SODIUM-HYDRO IMBALANCE	06FEB2014 /322	06FEB2014 /13	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0012/67 /M/W2/Y	Nervous system disorders/ Headache/ HEADACHE	01FEB2014* /317	14FEB2014 /21	C	1	0	1	5	1
207-0016/82 /F/W2/N	Gastrointestinal disorders/ Abdominal pain upper/ MILD RIGHT UPPER QUADRANT PAIN SYMPTOMS	06DEC2013 /57	19DEC2013 /-21	C	1	1	1	5	1
207-0017/81 /F/W2/N	General disorders and administration site conditions/ General physical health deterioration/ WORSENING OF GENERAL CONDITION	07MAR2014 /98	07MAR2014 /22	C	4	0	1	5 [PD]	5
	Gastrointestinal disorders/ Rectal prolapse/ RECTAL PROLAPSE	31JAN2014 /63	Unknown/NA	C	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0017/81 /F/W2/N	General disorders and administration site conditions/ Asthenia/ ASTENIA	17JAN2014 /49	30JAN2014 /-14	C	1	0	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ PERIPHERAL EDEMA LOWER LIMB	05DEC2013 /6	Unknown/NA	C	6	1	1	5	1
207-0019/55 /M/W2/Y	General disorders and administration site conditions/ Asthenia/ ASTENIA	17JUN2014 /14	Unknown/NA	C	6	1	1	5	2
	General disorders and administration site conditions/ Disease progression/ CLINICAL DISEASE PROGRESSION	20JUN2014 /17	25JUL2014 /38	C	4	1	2	5[Hepatocar cinoma]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
207-0019/55 /M/W2/Y	Infections and infestations/ Clostridiumdifficileinfection/ CLOSTRYDIUMDIFFICILIS INFECTION	25JUN2014 /22	Unknown/NA	C	6	1	1	5	3
209-0006/68 /M/W2/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	27MAY2013 /25	28MAY2013 /-224	I	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ STOMAC ACHE	30SEP2013 /151	30SEP2013 /-99	C	1	1	1	4	3
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT LOWER LIMB PAIN	30OCT2013 /181	26NOV2013 /-42	I	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
209-0006/68 /M/W2/N	Gastrointestinal disorders/ Abdominal pain upper/ STOMACHACHE	13MAY2013 /11	06JUN2013 /-215	I	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ PAIN IN RIGHT SHOULDER BLADE	09NOV2013 /191	21NOV2013 /-47	C	1	1	1	5	2
	Nervous system disorders/ Headache/ HEADACHE	11JUN2013 /40	18JUN2013 /-203	I	1	0	1	3	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	04FEB2014 /278	Unknown/NA	I	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
209-0006/68 /M/W2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	27MAY2013 /25	28MAY2013 /-224	I	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT LOWER LIMB PAIN	26NOV2013 /208	Unknown/NA	I	6	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ PAIN IN RIGHT SHOULDER BLADE	21NOV2013 /203	03DEC2013 /-35	I	1	0	1	5	1
	Nervous system disorders/ Hypoaesthesia/ HYPOESTHESIA AT RIGHT FOOT FINGERS	22OCT2013 /173	Unknown/NA	I	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
209-0006/68 /M/W2/N	Gastrointestinal disorders/ Abdominal pain upper/ STOMACH ACHE	29OCT2013 /180	29OCT2013 /-70	I	1	1	1	5	1
	General disorders and administration site conditions/ Asthenia/ ASTHENIA	26NOV2013 /208	Unknown/NA	C	6	0	1	4	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	01NOV2013* /183	14NOV2013 /-54	I	1	0	1	4	2
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT LOWER LIMB PAIN	22OCT2013 /173	29OCT2013 /-70	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
209-0006/68 /M/W2/N	Musculoskeletal and connective tissue disorders/ Back pain/ LOW BACK PAIN	11JUN2013 /40	Unknown/NA	I	6	0	1	4	1
209-0011/69 /M/W2/Y	Nervous system disorders/ Syncope/ POSTPRANDIAL SYNCOPÉ	08JAN2014 /36	08JAN2014 /-35	C	1	0	1	4	2
	Reproductive system and breast disorders/ Pelvic pain/ RIGHT PELVIS PAIN	01FEB2014* /60	Unknown/NA	I	6	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ LEFT SHOULDER BLADE PAIN	01FEB2014* /60	Unknown/NA	I	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
209-0014/80 /M/W2/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	18JUN2014 /93	Unknown/NA	I	6	1	1	4	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	29APR2014 /43	30APR2014 /-118	C	1	0	1	2	1
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastatic pain/ COSTO-VERTEBRAL PAIN (SITE OF METASTASES)	23AUG2014 /159	30SEP2014 /35	C	1	2	1	5	2
	Vascular disorders/ Flushing/ FLUSHING	21MAY2014 /65	21MAY2014 /-97	C	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
209-0014/80 /M/W2/N	Musculoskeletal and connective tissue disorders/ Back pain/ LEFT LUMBAR PAIN	24MAR2014 /7	25MAR2014 /-154	I	1	1	1	5	3
210-0003/74 /M/W2/Y	Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE PAIN	15NOV2013 /11	Unknown/NA	I	6	1	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	15NOV2013 /11	Unknown/NA	C	6	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	03DEC2013 /29	03DEC2013 /-3	I	1	0	1	5[Fever Not Related To Study Drug.]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
210-0003/74 /M/W2/Y	Metabolism and nutrition disorders/ Diabetes mellitus/ WORSENING OF DIABETES MELLITUS	05DEC2013 /31	17DEC2013 /11	C	1	1	2	5 [CD]	2
210-0005/53 /M/W2/N	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRALGIA	27MAY2014 /96	09JUN2014 /33	C	1	0	1	5	1
210-0006/45 /M/W2/N	Investigations/ Waist circumference increased/ INCREASED ABDOMINAL VOLUMETRY	10SEP2014 /79	Unknown/NA	C	6	0	1	5	1
	Hepatobiliary disorders/ Jaundice/ JAUNDICE	10SEP2014 /79	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
251-0002/69 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Epistaxis/ NOSEBLEED	17OCT2013 /65	17OCT2013 /9	I	1	0	1	3	1
	Infections and infestations/ Escherichia urinary tract infection/ URNINARY TRACT INFECTION, E-COLI	16OCT2013 /64	Unknown/NA	C	6	1	1	3	2
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	18SEP2013 /36	23SEP2013 /-15	I	1	0	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULOMONARY EMBOLUS	16OCT2013 /64	Unknown/NA	C	6	1	1	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
251-0002/69 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	20AUG2013 /7	Unknown/NA	I	6	0	1	3	1
	Investigations/ Blood albumin decreased/ DECREASED ALBUMIN	15OCT2013 /63	Unknown/NA	C	6	0	1	4	2
	Investigations/ Alanine aminotransferase increased/ ELEVATED ALT	15OCT2013 /63	Unknown/NA	C	6	0	1	4	2
	Gastrointestinal disorders/ Duodenal obstruction/ GASTRIC DUODENAL OBSTRUCTION	16OCT2013 /64	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
251-0002/69 /M/W2/N	Gastrointestinal disorders/ Ascites/ CLINICAL ASCITES	15OCT2013 /63	Unknown/NA	C	6	2	1	4[Possible Disease Progression , Ct On Week 12. Progression On Ct]	2
	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINEMIA	15OCT2013 /63	Unknown/NA	C	6	2	1	4[Possible Disease Progression But Not Due To Have Ct Scan Until Week 12. Ct Confirmed Progression ]	3
	Gastrointestinal disorders/ Vomiting/ VOMITING	07OCT2013 /55	07OCT2013 /-1	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
	Skin and subcutaneous tissue disorders/ Hyperhidrosis/ SWEATING	19SEP2013 /37	Unknown/NA	I	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
251-0002/69 /M/W2/N	Psychiatric disorders/ Depressed mood/ LOW MOOD	13AUG2013* /0	Unknown/NA	C	6	0	1	4	1
	Investigations/ Blood alkaline phosphatase increased/ ELEVATED ALK PHOS	15OCT2013 /63	Unknown/NA	C	6	0	1	4	3
	Gastrointestinal disorders/ Vomiting/ VOMIT	16OCT2013 /64	16OCT2013 /8	I	1	0	1	3	1
	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LOWER LIMB OEDEMA	15OCT2013 /63	Unknown/NA	C	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
251-0002/69 /M/W2/N	General disorders and administration site conditions/ Chest discomfort/ CHEST TIGHTNESS NOS	18SEP2013 /36	23SEP2013 /-15	C	1	1	1	3	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	22AUG2013 /9	Unknown/NA	I	6	0	1	3	1
	General disorders and administration site conditions/ Chest discomfort/ CHEST TIGHTNESS NOS	05SEP2013 /23	07SEP2013 /-31	I	1	1	1	4	1
	Investigations/ Aspartate aminotransferase increased/ ELEVATED AST	15OCT2013 /63	Unknown/NA	C	6	0	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
251-0003/68 /M/W2/N	Gastrointestinal disorders/ Vomiting/ VOMITING	13FEB2014 /100	13FEB2014 /-61	I	1	0	1	4	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ RIGHT SIDED MUSCULAR PAIN	04JAN2014 /60	Unknown/NA	C	6	1	1	3	1
	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINAEMIA	10DEC2013 /35	17DEC2013 /-119	C	1	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	29NOV2013 /24	Unknown/NA	C	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
251-0003/68 /M/W2/N	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	12NOV2013 /7	Unknown/NA	C	6	1	1	3	2
	Metabolism and nutrition disorders/ Hypomagnesaemia/ HYPOMAGNESEMIA	12NOV2013 /7	19NOV2013 /-147	C	1	1	1	3	1
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	12NOV2013 /7	19NOV2013 /-147	C	1	1	1	3	2
	Musculoskeletal and connective tissue disorders/ Myalgia/ RIGHT SIDED MUSCULAR PAIN	23DEC2013 /48	27DEC2013 /-109	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
251-0003/68 /M/W2/N	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LEG OEDEMA	19NOV2013 /14	25NOV2013 /-141	C	1	1	3 /19NOV2013 /26NOV2013	4	3
	General disorders and administration site conditions/ Oedema peripheral/ BILATERAL LEG OEDEMA	26NOV2013 /21	03DEC2013 /-133	C	1	1	1	4	1
252-0001/65 /M/A3/N	Gastrointestinal disorders/ Diarrhoea/ LOOSE STOOLS	22MAY2012 /14	22MAY2012 /-35	I	1	0	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ LOOSE STOOLS	06JUL2012 /59	06JUL2012 /10	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0001/65 /M/A3/N	Musculoskeletal and connective tissue disorders/ Back pain/ PAIN IN BACK (LEFT SIDE OF SPINE)	19MAY2012 /11	Unknown/NA	C	6	1	1	5	1
	Eye disorders/ Ocular hyperaemia/ BLOOD SHOT RIGHT EYE	14MAY2012 /6	17MAY2012 /-40	C	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Joint swelling/ SWELLING OF RIGHT FIRST METATARSOPHALANGEAL JOINT	12MAY2012 /4	20MAY2012 /-37	C	1	1	1	3	1
	General disorders and administration site conditions/ Influenza like illness/ FLU-LIKE SYMPTOMS	13MAY2012 /5	16MAY2012 /-41	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0001/65 /M/A3/N	Musculoskeletal and connective tissue disorders/ Muscular weakness/ BILATERAL LEG WEAKNESS	01JUL2012* /54	Unknown/NA	C	6	2	2	3	3
	Musculoskeletal and connective tissue disorders/ Joint swelling/ ANKLE SWELLING	10MAY2012 /2	18MAY2012 /-39	C	1	0	1	3	1
252-0004/50 /M/A1/N	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIGHT SHOULDER TIP PAIN	01JUL2013* /34	Unknown/NA	I	5	1	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	13AUG2013 /77	Unknown/NA	I	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0004/50 /M/A1/N	Investigations/ Weight decreased/ WEIGHT LOSS	30JUL2013 /63	Unknown/NA	C	6	1	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANAEMIA	30JUL2013 /63	Unknown/NA	C	5	1	1	3	1
	Gastrointestinal disorders/ Dysphagia/ DYSPHAGIA	24JUL2013 /57	Unknown/NA	I	5	0	1	4	1
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	20JUL2013 /53	Unknown/NA	I	5	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0006/64 /M/W2/N	General disorders and administration site conditions/ Chills/ RIGOR	12OCT2013 /11	12OCT2013 /-150	C	1	0	1	4	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	29JAN2014 /120	Unknown/NA	C	6	0	1	3	1
	Skin and subcutaneous tissue disorders/ Rash/ RASH (NOS)	01APR2014 /182	Unknown/NA	C	2	0	1	4	1
	Nervous system disorders/ Tremor/ RESTING HAND TREMOR	01OCT2013* /0	Unknown/NA	C	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0006/64 /M/W2/N	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	16NOV2013 /46	Unknown/NA	C	6	0	1	5	1
	Investigations/ Electrocardiogram ST segment depression/ LATERAL ST DEPLETION V5, V6 IN EXERCISE TOLERANCE TEST	13JAN2014 /104	14JAN2014 /-56	I	1	0	1	4	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	05OCT2013 /4	07OCT2013 /-155	I	1	0	1	3	2
	Infections and infestations/ Lower respiratory tract infection/ CHEST INFECTION	04OCT2013 /3	11OCT2013 /-151	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0006/64 /M/W2/N	Investigations/ Blood bilirubin increased/ RAISED BILIRUBIN	08OCT2013 /7	15OCT2013 /-147	C	1	0	1	4	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	16NOV2013 /46	18NOV2013 /-113	C	1	0	1	3	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	06MAR2014 /156	07MAR2014 /-4	I	1	0	1	3	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	16NOV2013 /46	18NOV2013 /-113	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0006/64 /M/W2/N	Nervous system disorders/ Dizziness/ DIZZINESS	23NOV2013 /53	23NOV2013 /-108	I	1	0	1	4	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	06OCT2013 /5	07OCT2013 /-155	I	1	1	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	14JAN2014 /105	Unknown/NA	C	6	1	1	4	1
	Eye disorders/ Vision blurred/ BLURRY VISION	18FEB2014 /140	17APR2014 /37	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0006/64 /M/W2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	16NOV2013 /46	18NOV2013 /-113	C	1	0	1	3	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	16NOV2013 /46	18NOV2013 /-113	C	1	1	1	3	1
	Infections and infestations/ Lower respiratory tract infection/ LOWER RESPIRATORY TRACT INFECTION	27NOV2013 /57	18JAN2014 /-52	I	1	1	1	4	1
252-0008/76 /M/W2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	09AUG2014 /74	09AUG2014 /-3	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0008/76 /M/W2/N	Musculoskeletal and connective tissue disorders/ Back pain/ LOWER BACK PAIN	09JUL2014 /43	Unknown/NA	C	6	1	1	4	1
	Gastrointestinal disorders/ Abdominal distension/ DISTENDED ABDOMEN	15JUL2014 /49	01AUG2014 /-11	C	1	0	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	29JUL2014 /63	29JUL2014 /-14	I	1	0	1	2	1
252-0010/56 /F/W2/N	General disorders and administration site conditions/ Oedema peripheral/ LEG OEDEMA	16DEC2014 /42	Unknown/NA	I	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0010/56 /F/W2/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	10DEC2014 /36	Unknown/NA	I	6	0	1	4	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	18NOV2014 /14	18NOV2014 /-63	I	1	1	1	3	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	17NOV2014 /13	19NOV2014 /-62	I	1	1	1	4	1
	Hepatobiliary disorders/ Hepatic pain/ LIVER CAPSULE PAIN	18NOV2014 /14	20NOV2014 /-61	C	1	1	3 /18NOV2014 /25NOV2014	4[PD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
252-0010/56 /F/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	10JAN2015 /67	Unknown/NA	C	6	0	3 /13JAN2015 /20JAN2015	3	2
	Metabolism and nutrition disorders/ Decreased appetite/ LOW APPETITE	16DEC2014 /42	Unknown/NA	I	6	0	1	4	1
253-0003/75 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	02JUL2012 /17	Unknown/NA	C	6	0	1	2	1
253-0004/79 /M/W2/N	Eye disorders/ Entropion/ WORSENING OF ENTROPION	23NOV2012 /77	Unknown/NA	C	5	3	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0004/79 /M/W2/N	Musculoskeletal and connective tissue disorders/ Back pain/ LOWER BACK PAIN	21DEC2012 /105	18JAN2013 /63	I	1	0	1	5	2
	Eye disorders/ Trichiasis/ TRICHIASIS	23NOV2012 /77	Unknown/NA	C	5	3	1	4	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	21DEC2012 /105	18JAN2013 /63	I	1	0	1	5	2
	Infections and infestations/ Nasopharyngitis/ COMMON COLD	12SEP2012 /5	05OCT2012 /-42	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0004/79 /M/W2/N	Gastrointestinal disorders/ Oesophageal spasm/ THROAT SPASM	21DEC2012 /105	Unknown/NA	I	5	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea exertional/ SHORT OF BREATH ON EXERTION	18DEC2012 /102	Unknown/NA	C	6	1	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ DECREASED APPETITE	01DEC2012* /85	31DEC2012* /45	C	1	0	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	01DEC2012* /85	31DEC2012* /45	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0004/79 /M/W2/N	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ DULL ACHE AROUND RIBS	26OCT2012 /49	09NOV2012 /-7	C	1	1	1	5	2
	General disorders and administration site conditions/ Injection site bruising/ BRUISING AT INJECTION SITE	12OCT2012 /35	26OCT2012 /-21	C	1	0	1	5	1
	Gastrointestinal disorders/ Eructation/ BELCHING	21DEC2012 /105	Unknown/NA	I	5	0	1	4	1
	Infections and infestations/ Lower respiratory tract infection/ CHEST INFECTION	18DEC2012 /102	Unknown/NA	C	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0004/79 /M/W2/N	Infections and infestations/ Conjunctivitis/ CONJUNCTIVITIS	19NOV2012 /73	Unknown/NA	C	5	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Muscle twitching/ TWITCHING IN UPPER ARM POST INJECTION	07SEP2012 /0	07SEP2012 /-70	C	1	0	1	4	1
	Skin and subcutaneous tissue disorders/ Skin lesion/ SKIN LESION FROM UNHEALED SHAVING CUT	30NOV2012 /84	Unknown/NA	C	5	1	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITED ONCE	01DEC2012* /85	31DEC2012* /45	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0005/74 /F/W2/N	Metabolism and nutrition disorders/ Hypercalcaemia/ HYPERCALCAEMIA	07NOV2012 /5	15NOV2012 /13	C	1	3	2	4 [CD]	3
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINAEMIA	07NOV2012 /5	15NOV2012 /13	C	1	2	1	3	2
	Investigations/ Inflammatory marker increased/ RAISED INFLAMMATORY MARKERS	07NOV2012 /5	15NOV2012 /13	C	1	3	1	4	3
	General disorders and administration site conditions/ Pyrexia/ PYREXIA	07NOV2012 /5	15NOV2012 /13	I	1	3	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0006/63 /M/A3/N	Eye disorders/ Dry eye/ DRY EYES	22MAR2013 /84	27MAR2013 /-51	C	1	0	1	5	1
253-0011/67 /M/W2/N	Gastrointestinal disorders/ Vomiting/ VOMITING	29JAN2015 /115	30JAN2015 /-157	I	1	0	1	3	1
	Gastrointestinal disorders/ Stomatitis/ STOMATITIS	19JAN2015 /105	25JAN2015 /-162	C	1	0	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	24NOV2014 /49	14DEC2014 /-204	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0011/67 /M/W2/N	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHY SKIN	09DEC2014 /64	10DEC2014 /-208	C	1	1	1	4	1
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHY SKIN	09JAN2015 /95	19JAN2015 /-168	C	1	1	1	5	1
	Renal and urinary disorders/ Dysuria/ DYSURIA	05JAN2015 /91	23FEB2015 /-133	C	1	0	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ ANKLE OEDEMA	12JAN2015 /98	19JAN2015 /-168	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0011/67 /M/W2/N	Metabolism and nutrition disorders/ Decreased appetite/ LOSS OF APPETITE	20OCT2014 /14	Unknown/NA	C	6	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain lower/ LOWER ABDOMEN DULL ACHE	20OCT2014 /14	Unknown/NA	I	6	0	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ DECREASED APPETITE	24NOV2014 /49	05JAN2015 /-182	C	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Back pain/ INTERMITTENT BACK PAIN	20OCT2014 /14	Unknown/NA	I	6	1	1	5	

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0011/67 /M/W2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	02NOV2014 /27	30NOV2014 /-218	I	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Arthralgia/ MUSCULAR SKELETAL KNEE PAIN	29DEC2014 /84	Unknown/NA	C	6	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	01DEC2014 /56	22DEC2014 /-196	C	1	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	20OCT2014 /14	Unknown/NA	C	6	0	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0011/67 /M/W2/N	Gastrointestinal disorders/ Gastric ulcer/ GASTRIC ULCER	06DEC2014 /61	Unknown/NA	C	6	1	1	4	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	13OCT2014 /7	Unknown/NA	C	6	1	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	15DEC2014 /70	16FEB2015 /-140	I	1	0	1	2	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	01DEC2014 /56	14DEC2014 /-204	C	1	0	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0011/67 /M/W2/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	29NOV2014 /54	30NOV2014 /-218	C	1	1	1	4	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	02FEB2015 /119	16FEB2015 /-140	I	1	1	1	3	1
	Psychiatric disorders/ Insomnia/ POOR SLEEP (INSOMNIA)	01DEC2014* /56	16FEB2015 /-140	C	1	1	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ MODERATE ITCH	02FEB2015 /119	16FEB2015 /-140	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0011/67 /M/W2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	01DEC2014 /56	04JAN2015 /-183	I	1	1	1	5	1
	Nervous system disorders/ Dysgeusia/ DYSGEUSIA (LACK OF TASTE)	01APR2015* /177	Unknown/NA	C	6	0	1	5	1
	Blood and lymphatic system disorders/ Iron deficiency anaemia/ IRON-DEFICIENCY ANAEMIA	26MAY2015 /232	Unknown/NA	C	6	1	1	5	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	29DEC2014 /84	12JAN2015 /-175	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0011/67 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	08JUN2015 /245	Unknown/NA	C	6	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	01MAY2015* /207	07JUN2015 /-29	C	1	0	1	5	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	23MAR2015 /168	30MAR2015 /-98	C	1	0	1	3	1
	Infections and infestations/ Escherichia infection/ ESCHERICIA COLI INFECTION URINE	09FEB2015 /126	23FEB2015 /-133		1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0011/67 /M/W2/N	Metabolism and nutrition disorders/ Decreased appetite/ DECREASED APPETITE	02FEB2015 /119	16MAR2015 /-112	I	1	0	1	3	1
	Renal and urinary disorders/ Nocturia/ NOCTURIA	02MAR2015 /147	Unknown/NA	I	6	0	1	5	1
253-0012/67 /M/W2/N	General disorders and administration site conditions/ Injection site pain/ SLIGHT PAIN AT INJECTION SITE	15DEC2014 /7	22DEC2014 /-14	C	1	0	1	1	1
	Respiratory, thoracic and mediastinal disorders/ Atelectasis/ ATELECTASIS	17JAN2015 /40	Unknown/NA	C	6	3	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0012/67 /M/W2/N	General disorders and administration site conditions/ Malaise/ MALAISE	12JAN2015 /35	Unknown/NA	C	6	0	1	5	2
	General disorders and administration site conditions/ Malaise/ MALAISE	05JAN2015 /28	12JAN2015 /7	C	1	0	1	5	1
	Psychiatric disorders/ Stress/ STRESS	05JAN2015 /28	Unknown/NA	C	6	0	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	29DEC2014 /21	Unknown/NA	I	6	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0012/67 /M/W2/N	Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	12JAN2015 /35	20JAN2015 /15	C	3	2	1	4	2
	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT PAIN	08DEC2014 /0	Unknown/NA	I	6	1	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	29DEC2014 /21	Unknown/NA	C	6	1	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	05JAN2015 /28	Unknown/NA	C	6	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
253-0012/67 /M/W2/N	General disorders and administration site conditions/ Application site rash/ RASH AROUND PLASTER SITE	08DEC2014 /0	22DEC2014 /-14	C	1	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	29DEC2014 /21	04JAN2015 /-1	I	1	0	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DISEASE PROGRESSION-SHORTNESS OF BREATH	12JAN2015 /35	20JAN2015 /15	C	4	0	2	4 [PD]	3
257-0005/66 /M/W2/N	Psychiatric disorders/ Insomnia/ INSOMNIA	10MAR2013 /66	Unknown/NA	I	6	3	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0005/66 /M/W2/N	Gastrointestinal disorders/ Dry mouth/ DRY MOUTH	10MAR2013 /66	Unknown/NA	C	6	0	1	1	1
	General disorders and administration site conditions/ Influenza like illness/ FLU-LIKE SYMPTOMS	10MAR2013 /66	Unknown/NA	C	6	0	1	1	1
	Infections and infestations/ Lower respiratory tract infection/ LOWER RESPIRATORY TRACT INFECTION	24JAN2013 /21	27FEB2013 /-15	C	1	1	1	4	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	03JAN2013 /0	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0005/66 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	03JAN2013 /0	23JAN2013 /-50	C	3	0	1	5	1
257-0013/63 /M/W2/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	15JUN2013 /16	Unknown/NA	I	6	0	1	4	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	15JUN2013 /16	Unknown/NA	C	6	0	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	14JUN2013 /15	Unknown/NA	I	6	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0013/63 /M/W2/N	Psychiatric disorders/ Insomnia/ INSOMNIA	10JUN2013 /11	Unknown/NA	I	6	1	1	4	1
	Skin and subcutaneous tissue disorders/ Palmar-plantar erythrodysaesthesia syndrome/ PALMAR PLANTAR ERYTHRODYSESTHESIA	07JUN2013 /8	Unknown/NA	C	6	0	1	3	2
	Skin and subcutaneous tissue disorders/ Rash/ BILATERAL RASH ON BACKS OF HANDS	07JUN2013 /8	Unknown/NA	C	6	0	1	3	2
	Gastrointestinal disorders/ Ascites/ INCREASING ASCITES	01JUL2013 /32	Unknown/NA	C	6	3	2	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0013/63 /M/W2/N	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	25JUN2013 /26	Unknown/NA	C	6	0	1	4	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	25JUN2013 /26	Unknown/NA	C	6	0	1	4	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	25JUN2013 /26	Unknown/NA	C	6	0	1	4	1
257-0020/72 /M/A1/Y	Infections and infestations/ Liver abscess/ WORSENING LIVER ABSCESS	20NOV2014 /24	25NOV2014 /8	C	1	1	2	5 [CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0020/72 /M/A1/Y	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ WORSENING LOWER ABDOMINAL PAIN	10NOV2014 /14	30NOV2014 /13	C	3	1	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	10NOV2014 /14	Unknown/NA	C	6	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIGHT SHOULDER PAIN	10NOV2014 /14	Unknown/NA	C	6	0	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING	03NOV2014 /7	Unknown/NA	I	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
257-0020/72 /M/A1/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	03NOV2014 /7	10NOV2014 /-7	C	1	0	1	3	1
	Nervous system disorders/ Dizziness/ DIZZINESS	08DEC2014 /42	Unknown/NA	I	6	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain lower/ LOWER ABDOMINAL PAIN	01DEC2014 /35	08DEC2014 /21	I	1	1	1	5	1
258-0002/69 /F/W2/Y	General disorders and administration site conditions/ Oedema/ ANKLE PITTING OEDEMA	10JUL2013 /89	24JUL2013 /-140	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0002/69 /F/W2/Y	Investigations/ Weight decreased/ WEIGHT LOSS	30OCT2013 /201	Unknown/NA	C	6	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	04NOV2013 /206	11NOV2013 /-30	C	1	0	3 /06NOV2013 /20NOV2013	5	2
	Cardiac disorders/ Tachycardia/ TACHYCARDIA	04NOV2013 /206	11NOV2013 /-30	I	1	0	3 /06NOV2013 /20NOV2013	5	1
	Nervous system disorders/ Syncope/ FAINTED - ONE EPISODE	28OCT2013 /199	28OCT2013 /-44	I	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0002/69 /F/W2/Y	Infections and infestations/ Lower respiratory tract infection/ CHEST INFECTION	22OCT2013 /193	30OCT2013 /-42	C	1	1	1	4	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	11OCT2013 /182	12OCT2013 /-60	C	1	0	1	4	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	28SEP2013 /169	15OCT2013 /-57	I	1	0	1	4	2
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	04SEP2013 /145	Unknown/NA	I	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0002/69 /F/W2/Y	Infections and infestations/ Lower respiratory tract infection/ CHEST INFECTION	11SEP2013 /152	12OCT2013 /-60	C	1	1	1	5	2
	Infections and infestations/ Oral herpes/ COLD SORE UNDER RIGHT NOSTRIL	13SEP2013 /154	02OCT2013 /-70	C	1	0	1	5	1
	Renal and urinary disorders/ Nocturia/ INCREASED MICTURITION AT NIGHT	10JUL2013 /89	30SEP2013* /-72	I	1	0	1	4	1
	Infections and infestations/ Lower respiratory tract infection/ CHEST INFECTION	29AUG2013 /139	04SEP2013 /-98	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0002/69 /F/W2/Y	General disorders and administration site conditions/ Feeling hot/ FEET FEEL HOT WHEN IN BED	19AUG2013 /129	21AUG2013 /-112	I	1	0	1	4	1
	Gastrointestinal disorders/ Dyspepsia/ INDIGESTION	14AUG2013 /124	21AUG2013 /-112	I	1	1	1	4	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	02AUG2013 /112	15AUG2013 /-118	I	1	1	1	2	1
	Infections and infestations/ Lower respiratory tract infection/ CHEST INFECTION	24JUL2013 /103	06AUG2013 /-127	C	1	3	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0002/69 /F/W2/Y	Metabolism and nutrition disorders/ Decreased appetite/ POOR APETITE	14JUL2013 /93	15AUG2013 /-118	I	1	1	1	4	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	14JUL2013 /93	18JUL2013 /-146	I	1	0	1	4	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	14JUL2013 /93	15AUG2013 /-118	I	1	1	1	4	2
	Renal and urinary disorders/ Micturition urgency/ MITRUITION URGENCY	10JUL2013 /89	30SEP2013* /-72	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0002/69 /F/W2/Y	Investigations/ Electrocardiogram abnormal/ ISCHAEMIC CHANGES IN ECG	26JUN2013 /75	10JUL2013 /-154	I	1	0	1	4	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	24JUN2013 /73	26JUN2013 /-168	C	1	0	1	4	1
	Eye disorders/ Vision blurred/ BLURRED VISION - LEFT EYE ONLY	01MAY2013* /19	01JUL2013 /-163	I	1	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Pleuritic pain/ PLEURITIC PAIN RIGHT SIDE	11JUN2013 /60	14JUN2013 /-180	I	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0002/69 /F/W2/Y	Gastrointestinal disorders/ Vomiting/ VOMITING	22OCT2013 /193	23DEC2013 /12	I	1	1	1	4	1
	General disorders and administration site conditions/ Injection site pain/ PAIN IN LEFT LEG OF INJECTION SITE, LEFT ARM AND RIGHT ARM	05JUN2013 /54	06JUN2013 /-188	C	1	0	1	2	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ CHESTY COUGH	29MAY2013 /47	Unknown/NA	I	6	0	1	5	1
	Infections and infestations/ Nasopharyngitis/ HEAD COLD SYMPTOMS	28MAY2013 /46	29MAY2013 /-196	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0002/69 /F/W2/Y	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	04MAY2013 /22	14JUN2013 /-180	I	1	0	1	3	1
	General disorders and administration site conditions/ Feeling hot/ WARM SENSATION LOWER STERNUM AREA	24APR2013 /12	Unknown/NA	I	6	0	1	2	1
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ ACHE IN RIGHT LOWER BUTTOCK, 25 MINUTES POST INJECTION RIGHT THIGH	24APR2013 /12	24APR2013 /-231	C	1	0	1	2	1
	Infections and infestations/ Pneumonia/ PNEUMONIA	03NOV2013 /205	11NOV2013 /-30	I	1	1	3 /06NOV2013 /20NOV2013	4[CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0002/69 /F/W2/Y	Nervous system disorders/ Lethargy/ LETHARGY	18APR2013 /6	21AUG2013 /-112	I	1	0	1	3	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	18APR2013 /6	19APR2013 /-236	C	1	0	1	3	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	19APR2013 /7	21APR2013 /-234	C	1	0	1	3	1
	Infections and infestations/ Lower respiratory tract infection/ CHEST INFECTION	17APR2013 /5	20APR2013 /-235	I	3	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0003/67 /F/W2/Y	Nervous system disorders/ Headache/ HEADACHE	25OCT2013 /161	01JAN2014 /70	I	1	1	1	4	3
	Gastrointestinal disorders/ Nausea/ NAUSEA	06NOV2013 /173	Unknown/NA	C	6	1	1	4	3
	Respiratory, thoracic and mediastinal disorders/ Rales/ FINE CRACKLES BOTH BASES - LUNGS	09OCT2013 /145	23OCT2013 /0	C	1	0	1	4	1
	Musculoskeletal and connective tissue disorders/ Joint swelling/ SWOLLEN ANKLES	23SEP2013 /129	25DEC2013 /63	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0003/67 /F/W2/Y	Hepatobiliary disorders/ Hepatic pain/ 'LIVER PAIN'	30SEP2013 /136	Unknown/NA	I	6	1	1	4[? Liver Inflammatio n]	2
	Gastrointestinal disorders/ Abdominal pain upper/ UPPER LEFT QUADRANT PAIN	23SEP2013 /129	26SEP2013 /-27	I	1	0	1	4	2
	Respiratory, thoracic and mediastinal disorders/ Pleuritic pain/ PLEURITIC CHEST PAIN	20SEP2013 /126	01OCT2013 /-22	I	1	1	1	4	2
	Nervous system disorders/ Tremor/ SHAKING (AT NIGHT)	23SEP2013 /129	03OCT2013 /-20	I	1	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0003/67 /F/W2/Y	Infections and infestations/ Lower respiratory tract infection/ CHEST INFECTION	23SEP2013 /129	01OCT2013 /-22	I	1	1	3 /25SEP2013 /02OCT2013	4[Bacterial Susceptabil ity]	3
	Gastrointestinal disorders/ Abdominal pain/ SHARP PAIN, FRONT OF ABDOMEN	13SEP2013 /119	Unknown/NA	I	6	0	1	4	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	12SEP2013 /118	06OCT2013 /-17	C	1	1	1	4	2
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea exertional/ BREATHLESS ON EXERTION	16AUG2013 /91	Unknown/NA	I	6	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0003/67 /F/W2/Y	Gastrointestinal disorders/ Abdominal distension/ SWOLLEN ABDOMEN	16AUG2013 /91	Unknown/NA	C	6	0	1	4	1
	General disorders and administration site conditions/ Oedema peripheral/ SLIGHT OEDEMA LOWER LEGS AND FEET	16AUG2013 /91	11SEP2013 /-42	C	1	0	1	4	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	16AUG2013 /91	17AUG2013 /-67	I	1	1	1	4	1
	General disorders and administration site conditions/ Catheter site pain/ PAIN - POST PIGTAIL CATHETER REMOVAL	16AUG2013 /91	27AUG2013 /-57	I	1	1	3 /23JUL2013 /16AUG2013	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0003/67 /F/W2/Y	Injury, poisoning and procedural complications/ Procedural pain/ PAIN - POST BILIARY STENT INSERTION	14AUG2013 /89	15AUG2013 /-69	I	1	1	3 /23JUL2013 /16AUG2013	5	3
	Investigations/ Blood bilirubin increased/ RAISED BILIRUBIN	07AUG2013 /82	23AUG2013 /-61	C	1	0	3 /23JUL2013 /16AUG2013	5	3
	Investigations/ Alanine aminotransferase increased/ ELEVATED ALT	07AUG2013 /82	23AUG2013 /-61	C	1	0	3 /07AUG2013 /16AUG2013	5	3
	Investigations/ Aspartate aminotransferase increased/ ELEVATED AST	07AUG2013 /82	23AUG2013 /-61	C	1	0	3 /07AUG2013 /16AUG2013	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0003/67 /F/W2/Y	Investigations/ Blood alkaline phosphatase increased/ ELEVATED ALK PHOS	07AUG2013 /82	23AUG2013 /-61	C	1	0	3 /07AUG2013 /16AUG2013	5	3
	Gastrointestinal disorders/ Nausea/ NAUSEA	18JUL2013 /62	10AUG2013 /-74	I	1	1	1	3	2
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITIS	03AUG2013 /78	15AUG2013 /-69	C	1	1	3 /07AUG2013 /16AUG2013	5	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	05AUG2013 /80	14AUG2013 /-70	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0003/67 /F/W2/Y	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	18JUL2013 /62	28JUL2013 /-87	I	1	0	1	5	2
	Infections and infestations/ Hepatobiliary infection/ HEPTOBILIARY INFECTION	24JUL2013 /68	06AUG2013 /-78	C	1	1	3 /24JUL2013 /16AUG2013	4	2
	Investigations/ Blood bilirubin increased/ RAISED BILIRUBIN	24JUL2013 /68	31JUL2013 /-84	C	2	0	3 /24JUL2013 /16AUG2013	4	2
	Investigations/ Alanine aminotransferase increased/ RAISED ALT	17JUL2013 /61	31JUL2013 /-84	C	2	0	3 /24JUL2013 /16AUG2013	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0003/67 /F/W2/Y	Investigations/ Aspartate aminotransferase increased/ RAISED AST	17JUL2013 /61	31JUL2013 /-84	C	2	0	3 /24JUL2013 /16AUG2013	4	3
	Investigations/ Blood alkaline phosphatase increased/ RAISED ALK PHOS	17JUL2013 /61	31JUL2013 /-84	C	2	0	3 /24JUL2013 /16AUG2013	4	3
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITIS	18JUL2013 /62	28JUL2013 /-87	I	1	0	1	5	1
	Hepatobiliary disorders/ Jaundice/ JAUNDICE	18JUL2013 /62	23AUG2013 /-61	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0003/67 /F/W2/Y	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	18JUL2013 /62	18AUG2013 /-66	C	1	1	1	3	3
	Hepatobiliary disorders/ Bile duct obstruction/ BILIARY DUCT OBSTRUCTION	07AUG2013 /82	14AUG2013 /-70	C	1	3	3 /24JUL2013 /23AUG2013	5[The Disease In The Liver Caused The Ae.]	3
	Immune system disorders/ Seasonal allergy/ HAY FEVER	15JUL2013 /59	12SEP2013 /-41	I	1	1	1	4	1
	General disorders and administration site conditions/ Fatigue/ TIREDNESS	17MAY2013 /0	Unknown/NA	I	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0004/66 /M/W2/N	Reproductive system and breast disorders/ Scrotal oedema/ SCROTAL OEDEMA	21JUN2013 /30	Unknown/NA	C	6	0	1	5	2
	Metabolism and nutrition disorders/ Fluid overload/ FLUID OVERLOAD SECONDARY TO LIVER DECOMPENSATION	12JUN2013 /21	Unknown/NA	C	6	3	1	4	2
	Psychiatric disorders/ Hallucination/ HALLUCINATIONS	19JUN2013 /28	21JUN2013 /30	I	1	0	1	5	2
	Infections and infestations/ Catheter site infection/ INFECTED CANNULA SITE RIGHT HAND	09JUN2013 /18	Unknown/NA	C	6	2	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0004/66 /M/W2/N	Blood and lymphatic system disorders/ Anaemia/ ANAEMIA	11JUN2013 /20	Unknown/NA	C	6	0	1	4	1
	Investigations/ Blood bilirubin increased/ RAISED BILIRUBIN	29MAY2013 /7	Unknown/NA	C	6	0	1	4	3
	Investigations/ International normalised ratio increased/ INCREASED INR	29MAY2013 /7	Unknown/NA	C	6	1	1	5	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	05JUN2013 /14	Unknown/NA	I	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0004/66 /M/W2/N	Investigations/ Weight increased/ WEIGHT GAIN	05JUN2013 /14	Unknown/NA	C	6	1	1	4	1
	Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	29MAY2013 /7	Unknown/NA	I	6	1	1	4	2
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	29MAY2013 /7	Unknown/NA	C	6	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEG PAIN	30MAY2013 /8	Unknown/NA	C	6	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0004/66 /M/W2/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ INCREASED SHORTNESS OF BREATH	28MAY2013 /6	Unknown/NA	I	6	0	1	4	2
	Infections and infestations/ Cellulitis/ WORSENING OF CELLULITIS	29MAY2013 /7	Unknown/NA	C	6	1	1	4	3
	Metabolism and nutrition disorders/ Fluid overload/ FLUID OVERLOAD	29MAY2013 /7	11JUN2013 /20	C	2	3	2	4[Underlyin g Liver Disease (Hepatic Decompensat ion)]	3
	General disorders and administration site conditions/ Oedema peripheral/ PERIPHERAL OEDEMA	29MAY2013 /7	Unknown/NA	C	6	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0004/66 /M/W2/N	General disorders and administration site conditions/ Pyrexia/ PYREXIA	29MAY2013 /7	Unknown/NA	I	6	1	1	4	1
258-0006/69 /M/W2/N	Blood and lymphatic system disorders/ Anaemia/ ANAEMIA	08NOV2013 /24	15NOV2013 /21	C	1	1	2	4	3
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	15NOV2013 /31	Unknown/NA	C	6	1	3 /01NOV2013 /Unknown	5[CD]	3
	Nervous system disorders/ Hypoaesthesia/ NUMB - RIGHT SIDE OF CHIN	27OCT2013 /12	Unknown/NA	C	6	0	1	4[Unknown Reason]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0006/69 /M/W2/N	Nervous system disorders/ Dizziness/ DIZZINESS	26OCT2013 /11	Unknown/NA	I	6	0	1	4[Unknown Cause]	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	26OCT2013 /11	Unknown/NA	I	6	1	1	3	1
	Injury, poisoning and procedural complications/ Laceration/ SKIN TEAR LEFT ARM	23OCT2013 /8	Unknown/NA	C	6	0	1	5	1
	Nervous system disorders/ Dysgeusia/ TASTE ALTERATION	19OCT2013 /4	Unknown/NA	I	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0006/69 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	21OCT2013 /6	Unknown/NA	I	6	0	1	3	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA (REDUCED APPETITE)	22OCT2013 /7	Unknown/NA	C	6	0	1	3	1
	Skin and subcutaneous tissue disorders/ Rash/ RASH - UPPER CHEST	18OCT2013 /3	Unknown/NA	C	6	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Back pain/ LOWER BACK PAIN - RIGHT SIDE	20OCT2013 /5	Unknown/NA	I	6	1	1	4 [CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0006/69 /M/W2/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	02NOV2013 /18	07NOV2013 /13	C	1	1	1	4 [CM]	2
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	30OCT2013 /15	01NOV2013 /7	C	2	1	1	4 [CM]	3
258-0013/59 /M/W2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	23JAN2015 /72	Unknown/NA	I	6	0	1	3	1
	Infections and infestations/ Nasopharyngitis/ COLD SYMPTOMS	17JAN2015 /66	02MAR2015 /33	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0013/59 /M/W2/N	Eye disorders/ Vision blurred/ OCCULAR- BLURRED VISION RIGHT EYE	05JAN2015 /54	05JAN2015 /-23	I	1	0	1	3	1
	Reproductive system and breast disorders/ Nipple pain/ PAINFUL LEFT NIPPLE	30DEC2014 /48	Unknown/NA	I	6	0	1	3	1
	Infections and infestations/ Lower respiratory tract infection/ CHEST INFECTION	29DEC2014 /47	05JAN2015 /-23	C	1	1	1	4	2
	Infections and infestations/ Nasopharyngitis/ COLD SYMPTOMS	27DEC2014 /45	28DEC2014 /-31	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0013/59 /M/W2/N	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITIS - ABDOMEN	20NOV2014 /8	Unknown/NA	I	6	0	1	4	1
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	15NOV2014 /3	11DEC2014 /-48	I	1	0	1	4	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	12NOV2014 /0	13NOV2014 /-76	C	1	0	1	3	2
	Musculoskeletal and connective tissue disorders/ Musculoskeletal discomfort/ RIGHT KNEE DISCOMFORT	12NOV2014 /0	13NOV2014 /-76	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
258-0013/59 /M/W2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	13NOV2014 /1	15NOV2014 /-74	I	1	1	1	3	1
259-0003/73 /M/W2/N	Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	17MAY2015 /340	Unknown/NA	C	6	1	3 /13MAY2015 /Unknown	5[CD]	3
	Cardiac disorders/ Cardiac failure congestive/ CONGESTIVE CARDIAC FAILURE (EXACERBATION OF)	11MAY2015 /334	16MAY2015 /10	C	3	1	3 /13MAY2015 /Unknown	5[CD]	3
	General disorders and administration site conditions/ Oedema peripheral/ ANKLE OEDEMA	15APR2015 /308	Unknown/NA	C	6	1	3 /22APR2015 /29APR2015	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0003/73 /M/W2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	01DEC2014 /173	02DEC2014 /-155	I	1	0	1	3	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	11MAR2015 /273	Unknown/NA	C	6	0	1	5	1
	Hepatobiliary disorders/ Hepatic pain/ LIVER PAIN	24DEC2014 /196	07JAN2015 /-119	I	1	0	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	07JAN2015 /210	07JAN2015 /-119	I	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0003/73 /M/W2/N	Infections and infestations/ Lower respiratory tract infection/ CHEST INFECTION	23FEB2015 /257	01MAR2015 /-66	C	1	1	1	5	3
	Vascular disorders/ Hypotension/ HYPOTENSION	11MAR2015 /273	11MAR2015 /-56	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	14FEB2015 /248	17FEB2015 /-78	I	1	1	1	5[Respirato ry Viral Infection]	3
	Psychiatric disorders/ Insomnia/ IMSOMNIA	28JAN2015 /231	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0003/73 /M/W2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	30JUL2014 /49	24SEP2014 /-224	I	1	0	1	3	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	10JUL2014 /29	11JUL2014 /-299	I	1	0	1	3	2
	Cardiac disorders/ Atrial fibrillation/ ATRIAL FIBRILLATION	15APR2015 /308	Unknown/NA	C	6	1	3 /22APR2015 /29APR2015	4	2
259-0004/52 /M/W2/N	Gastrointestinal disorders/ Vomiting/ VOMITING	27AUG2014 /35	Unknown/NA	I	6	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0004/52 /M/W2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	27AUG2014 /35	Unknown/NA	C	6	0	3 /27AUG2014 /Unknown	2	3
	Skin and subcutaneous tissue disorders/ Dry skin/ DRY SKIN - NECK	20AUG2014 /28	Unknown/NA	C	6	0	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	20AUG2014 /28	Unknown/NA	I	6	0	1	3	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	30JUL2014 /7	26AUG2014 /6	I	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0004/52 /M/W2/N	Gastrointestinal disorders/ Abdominal discomfort/ ABDOMINAL DISCOMFORT	06AUG2014 /14	Unknown/NA	I	6	1	1	4	1
	Skin and subcutaneous tissue disorders/ Eczema/ ECZEMATOUS PATCH RIGHT HIP	03AUG2014 /11	Unknown/NA	C	6	0	1	3	1
	Skin and subcutaneous tissue disorders/ Rash maculo-papular/ MACULOPAPULAR RASH	03AUG2014 /11	Unknown/NA	C	6	0	1	3	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	05AUG2014 /13	05AUG2014 /-15	I	1	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
259-0004/52 /M/W2/N	Gastrointestinal disorders/ Ascites/ ABDOMINAL ASCITES	23JUL2014 /0	Unknown/NA	C	6	1	1	5	1
260-0002/66 /M/W2/N	Gastrointestinal disorders/ Abdominal pain upper/ UPPER EPIGASTRIC PAIN	12FEB2014 /133	Unknown/NA	C	6	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ UPPER EPIGASTRIC PAIN	06NOV2013 /35	24JUL2014 /267	C	1	0	3 /06NOV2013 /Unknown	4	3
	Gastrointestinal disorders/ Constipation/ INTERMITTENT CONSTIPATION	15OCT2013 /13	Unknown/NA	I	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
260-0002/66 /M/W2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHOEA	07OCT2013 /5	13OCT2013 /-17	I	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Rash macular/ ERYTHEMATOUS MACULAR RASH RIGHT ARM	25OCT2013 /23	06NOV2013 /7	C	1	0	1	3	1
301-0001/47 /F/A2/Y	Nervous system disorders/ Dysgeusia/ MOUTH WEIRD TASTE	20NOV2011 /19	23NOV2011 /-55	I	1	0	1	3	1
	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	19JAN2012 /79	24JAN2012 /7	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
301-0001/47 /F/A2/Y	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	30DEC2011 /59	18APR2013 /457	I	1	0	1	5	1
301-0003/61 /F/A2/Y	Gastrointestinal disorders/ Abdominal pain upper/ WORSENING EPIGASTRALGIA	26APR2012 /56	28AUG2012 /103	I	1	1	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ WORSENING EDEMA LIMBS (LOWER LEG)	05APR2012 /35	28AUG2012 /103	I	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea exertional/ EXERTIONAL DYPNEA	05APR2012 /35	28AUG2012 /103	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
301-0003/61 /F/A2/Y	Musculoskeletal and connective tissue disorders/ Pain in extremity/ PAIN IN EXTREMITY	25MAR2012 /24	05APR2012 /-42	I	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	03MAR2012 /2	15MAR2012 /-63	I	1	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	22MAR2012 /21	28AUG2012 /103	C	1	0	1	5	2
	Gastrointestinal disorders/ Ascites/ ASCITES	17MAY2012 /77	28AUG2012 /103	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
301-0003/61 /F/A2/Y	Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING BACK PAIN	25MAR2012 /24	28AUG2012 /103	I	1	1	1	5	2
	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	08MAR2012 /7	15MAR2012 /-63	C	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	26APR2012 /56	17MAY2012 /0	I	1	0	1	5	1
301-0008/53 /M/A2/Y	Investigations/ Prothrombin time prolonged/ PROTHROMBIN TIME INCREASED	22MAR2013 /77	25APR2013 /48	C	1	3	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
301-0008/53 /M/A2/Y	Hepatobiliary disorders/ Jaundice/ JAUNDICE	15MAR2013 /70	22MAY2013 /75	C	1	2	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMB (LEG)	22FEB2013 /49	08MAR2013 /0	C	1	1	1	5	2
	Gastrointestinal disorders/ Gastritis/ GASTRITIS	01FEB2013 /28	22MAY2013 /75	C	1	1	1	5	2
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	22MAR2013 /77	22MAY2013 /75	C	1	0	1	4	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
301-0008/53 /M/A2/Y	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	22FEB2013 /49	22MAR2013 /14	C	2	0	1	4	3
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	24MAR2013 /79	22MAY2013 /75	C	1	1	1	5	3
	Metabolism and nutrition disorders/ Cachexia/ CACHEXIA	22MAR2013 /77	25APR2013 /48	C	1	1	3 /22MAR2013 /Unknown	5[PD]	3
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	08FEB2013 /35	22FEB2013 /-14	I	2	0	1	4	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
301-0008/53 /M/A2/Y	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	25JAN2013 /21	08FEB2013 /-28	C	1	0	1	4	3
	Infections and infestations/ Bronchitis/ BRONCHITIS	01MAR2013 /56	22MAY2013 /75	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Cachexia/ CACHEXIA	25APR2013 /111	22MAY2013 /75	C	1	1	1	5	2
	Cardiac disorders/ Tachycardia/ TACHYCARDIA	15MAR2013 /70	22MAY2013 /75	I	1	0	3 /15MAR2013 /Unknown	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
301-0008/53 /M/A2/Y	Psychiatric disorders/ Insomnia/ INSOMNIA	15MAR2013 /70	22MAY2013 /75	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	08MAR2013 /63	22MAY2013 /75	C	1	1	1	5	2
	General disorders and administration site conditions/ Pain/ GENERAL SORENESS	01MAR2013 /56	22MAY2013 /75	C	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	22FEB2013 /49	22MAY2013 /75	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
301-0008/53 /M/A2/Y	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	08FEB2013 /35	24MAR2013 /16	C	1	1	1	5	2
	Gastrointestinal disorders/ Inguinal hernia/ LEFT INGUINAL HERNIA	01FEB2013 /28	22MAY2013 /75	C	1	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	24JAN2013 /20	22MAR2013 /14	I	1	1	3 /08FEB2013 /15FEB2013	3	1
	Respiratory, thoracic and mediastinal disorders/ Epistaxis/ EPISTAXIS	18JAN2013 /14	25JAN2013 /-42	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
301-0008/53 /M/A2/Y	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	25JAN2013 /21	01MAR2013 /-7	C	1	1	1	5	2
	Blood and lymphatic system disorders/ Leukocytosis/ LEUKOCYTOSIS	07APR2013 /93	25APR2013 /48	C	1	1	1	5	2
302-0006/49 /M/A2/N	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	15MAR2012 /65	19MAR2012 /27	C	1	0	1	4	3
	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	15MAR2012 /65	24MAR2012 /32	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0006/49 /M/A2/N	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	15MAR2012 /65	24MAR2012 /32	C	1	0	1	5	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	12MAR2012 /62	15MAR2012 /23	C	1	0	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	08MAR2012 /58	12MAR2012 /20	C	1	0	1	5	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	14FEB2012 /35	08MAR2012 /16	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0006/49 /M/A2/N	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	05MAR2012 /55	24MAR2012 /32	C	1	0	1	5	1
	Investigations/ C-reactive protein increased/ C-REACTIVE PROTEIN INCREASED	02MAR2012 /52	24MAR2012 /32	C	1	0	1	5	1
	Investigations/ Gamma-glutamyltransferase increased/ GAMMA GLUTAMYL TRANSPEPTIDASE INCREASED	28FEB2012 /49	24MAR2012 /32	C	1	0	1	5	3
	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATEASE INCREASED	31JAN2012 /21	24MAR2012 /32	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0006/49 /M/A2/N	Investigations/ Blood lactate dehydrogenase increased/ LACTIC DEHYDROGENASE INCREASED	31JAN2012 /21	24MAR2012 /32	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	28FEB2012 /49	24MAR2012 /32	C	1	0	1	2	1
	Investigations/ Lymphocyte count decreased/ LYMPHOCYTE COUNT DECREASED	28FEB2012 /49	05MAR2012 /13	C	1	0	1	5	2
	Investigations/ Lymphocyte count decreased/ LYMPHOCYTE COUNT DECREASED	31JAN2012 /21	14FEB2012 /-7	C	1	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0006/49 /M/A2/N	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	19MAR2012 /69	24MAR2012 /32	C	1	0	1	4	1
	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	28FEB2012 /49	15MAR2012 /23	C	1	0	1	4	1
	Metabolism and nutrition disorders/ Hypercalcaemia/ HYPERCALCEMIA	14FEB2012 /35	28FEB2012 /7	C	1	0	1	4	1
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	31JAN2012 /21	28FEB2012 /7	C	1	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0006/49 /M/A2/N	Gastrointestinal disorders/ Ascites/ ASCITES	15MAR2012 /65	24MAR2012 /32	C	1	3	1	4	3
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	10MAR2012 /60	24MAR2012 /32	C	1	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Hiccups/ HICCUP	10MAR2012 /60	10MAR2012 /18	C	1	1	1	4	1
	Hepatobiliary disorders/ Hepatorenal syndrome/ HEPAORENAL SYNDROME	19MAR2012 /69	24MAR2012 /32	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0006/49 /M/A2/N	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	14MAR2012 /64	24MAR2012 /32	C	1	1	1	4	3
	Gastrointestinal disorders/ Ascites/ ASCITES	05MAR2012 /55	15MAR2012 /23	C	1	1	1	4	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	01MAR2012 /51	24MAR2012 /32	I	1	1	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Productive cough/ MUSH SPUTUM	29FEB2012 /50	01MAR2012 /9	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0006/49 /M/A2/N	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	06MAR2012 /56	24MAR2012 /32	I	1	0	1	5	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	28FEB2012 /49	24MAR2012 /32	I	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	11MAR2012 /61	24MAR2012 /32	I	1	2	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	01MAR2012 /51	15MAR2012 /23	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0006/49 /M/A2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	28FEB2012 /49	24MAR2012 /32	C	1	0	1	5	3
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH (ARM)	21FEB2012 /42	28FEB2012 /7	I	1	0	1	2	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	19JAN2012 /9	24MAR2012 /32	I	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	10JAN2012 /0	17FEB2012 /-4	I	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0006/49 /M/A2/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMEN PAIN	10JAN2012 /0	24MAR2012 /32	I	1	1	1	4	2
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	28FEB2012 /49	24MAR2012 /32	I	1	0	3 /13MAR2012 /Unknown	4 [PD]	3
	Metabolism and nutrition disorders/ Hypercalcaemia/ HYPERCALCEMIA	28FEB2012 /49	02MAR2012 /10	I	1	1	3 /28FEB2012 /Unknown	4 [PD]	2
302-0009/73 /M/A2/N	Investigations/ Blood creatinine increased/ CREATININE INCREASED	05JUN2012 /49	04JUL2012 /36	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0009/73 /M/A2/N	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	08MAY2012 /21	05JUN2012 /7	C	1	0	1	5	2
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	05JUN2012 /49	04JUL2012 /36	C	1	1	3 /05JUN2012 /Unknown	5	3
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	24APR2012 /7	04JUL2012 /36	C	1	0	1	4	1
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	08MAY2012 /21	05JUN2012 /7	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0009/73 /M/A2/N	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	05JUN2012 /49	04JUL2012 /36	C	1	0	1	5	2
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	05JUN2012 /49	04JUL2012 /36	C	1	1	3 /05JUN2012 /Unknown	5	3
302-0012/62 /M/A2/Y	Gastrointestinal disorders/ Melaena/ TARRY STOOL	07AUG2012 /105	21AUG2012 /42	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	31JUL2012 /98	07AUG2012 /28	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0012/62 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	31JUL2012 /98	07AUG2012 /28	C	1	1	1	5	1
	Gastrointestinal disorders/ Melaena/ TARRY STOOL	11JUL2012 /78	12JUL2012 /2	C	1	1	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	10JUL2012 /77	11OCT2012 /93	C	1	0	1	5	1
	Investigations/ Activatedpartial thromboplastin time prolonged/ ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED	10JUL2012 /77	14AUG2012 /35	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0012/62 /M/A2/Y	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	10JUL2012 /77	11OCT2012 /93	C	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	10JUL2012 /77	11OCT2012 /93	I	1	0	1	4	1
	Metabolism and nutrition disorders/ Hypocalcaemia/ HYPOCALCEMIA	26JUN2012 /63	11OCT2012 /93	C	1	0	1	5	1
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	26JUN2012 /63	09JUL2012 /-1	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0012/62 /M/A2/Y	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	12JUN2012 /49	25JUN2012 /-15	C	1	0	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	12JUN2012 /49	11OCT2012 /93	C	1	0	1	5	1
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	12JUN2012 /49	11OCT2012 /93	C	1	0	1	5	2
	Gastrointestinal disorders/ Duodenal ulcer/ DUODENAL ULCER	05JUN2012 /42	11OCT2012 /93	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0012/62 /M/A2/Y	Gastrointestinal disorders/ Gastric varices/ GASTRIC VARICES	05JUN2012 /42	11OCT2012 /93	C	1	0	1	5	1
	Gastrointestinal disorders/ Gastritis erosive/ EROSIVE GASTRITIS	05JUN2012 /42	11OCT2012 /93	C	1	1	1	5	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	05JUN2012 /42	11OCT2012 /93	I	1	1	1	4	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	05JUN2012 /42	11JUN2012 /-29	C	1	2	3 /05JUN2012 /12JUN2012	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0012/62 /M/A2/Y	Gastrointestinal disorders/ Melaena/ TARRY STOOL	01JUN2012 /38	12JUN2012 /-28	C	1	0	1	5	1
	Investigations/ Activatedpartial thromboplastin time prolonged/ ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED	15MAY2012 /21	12JUN2012 /-28	C	1	0	1	5	1
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	15MAY2012 /21	11OCT2012 /93	C	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	08MAY2012 /14	15MAY2012 /-56	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0012/62 /M/A2/Y	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	24APR2012 /0	01MAY2012 /-70	C	1	0	1	4	1
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	29MAY2012 /35	11JUN2012 /-29	C	1	0	1	5	1
	Infections and infestations/ Gingivitis/ GUM INFECTION	29MAY2012 /35	05JUN2012 /-35	C	1	1	1	4	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	08MAY2012 /14	15MAY2012 /-56	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0012/62 /M/A2/Y	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	29MAY2012 /35	11JUN2012 /-29	C	1	0	1	5	2
302-0013/62 /M/A2/Y	Psychiatric disorders/ Anxiety/ ANXIETY	14MAY2013 /49	14DEC2013 /200	C	1	1	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS (LEFT LEG)	28MAY2013 /63	02JUL2013 /35	C	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ PAIN (LEFT HIP)	30APR2013 /35	14DEC2013 /200	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0013/62 /M/A2/Y	Gastrointestinal disorders/ Constipation/ CONSTIPATION	09APR2013 /14	14DEC2013 /200	C	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ PAIN(LEFT HIP)	26MAR2013 /0	29APR2013 /-29	C	1	1	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	27MAR2013 /1	09APR2013 /-49	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	17APR2013 /22	30APR2013 /-28	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0020/52 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Hiccups/ HICCUPS	26JUN2013 /36	26JUN2013 /15	C	1	1	1	5	2
	Psychiatric disorders/ Anxiety/ ANXIETY	24JUN2013 /34	12SEP2013 /93	I	1	1	1	5	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	26JUN2013 /36	23NOV2013 /165	I	1	1	1	5	2
302-0021/75 /F/A2/Y	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	27OCT2013 /138	11NOV2013 /-8	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0021/75 /F/A2/Y	Infections and infestations/ Nasopharyngitis/ COMMON COLD	16JUL2013 /35	30JUL2013 /-112	C	1	1	1	4	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	05NOV2013 /147	26NOV2013 /7	I	1	0	1	4	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	15OCT2013 /126	14FEB2014 /87	C	1	1	1	4	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	08OCT2013 /119	14FEB2014 /87	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0021/75 /F/A2/Y	Infections and infestations/ Acute sinusitis/ ACUTE SINUSITIS	16JUL2013 /35	30JUL2013 /-112	C	1	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Bronchitis chronic/ CHRONIC BRONCHITIS	09JUL2013 /28	10SEP2013 /-70	I	1	1	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL CONGESTION	18JUN2013 /7	02JUL2013 /-140	I	1	0	1	4	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	25JUN2013 /14	05NOV2013 /-14	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
302-0021/75 /F/A2/Y	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	18JUN2013 /7	16JUL2013 /-126	C	1	1	3 /02JUL2013 /16JUL2013	4	3
	Musculoskeletal and connective tissue disorders/ Muscular weakness/ MUSCLE WEAKNESS LOWER LIMB	13JUN2013 /2	25JUN2013 /-147	C	1	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Sputum discoloured/ YELLOWISH SPUTUM	25JUN2013 /14	02JUL2013 /-140	C	1	1	1	4	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	13JUN2013 /2	02JUL2013 /-140	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
304-0003/56 /F/A2/N	Respiratory, thoracic and mediastinal disorders/ Hiccups/ HICCUP	29JUN2013 /107	29JUN2013 /30	I	1	0	1	5	1
	Injury, poisoning and procedural complications/ Procedural pain/ FOR POST OPERATION WOUND PAIN (ON PORT-A CATHER)	26JUN2013 /104	01JUL2013 /32	I	1	1	1	5	2
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	27JUN2013 /105	29JUN2013 /30	I	1	1	1	5	2
	General disorders and administration site conditions/ Chest discomfort/ CHEST TIGHTNESS (NOS)	27JUN2013 /105	28JUN2013 /29	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
304-0003/56 /F/A2/N	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	16MAY2013 /63	03JUL2013 /34	C	1	0	1	5	2
	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	17APR2013 /34	02MAY2013 /-28	C	1	0	1	5	1
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	03APR2013 /20	02MAY2013 /-28	C	1	0	1	5	1
304-0004/69 /M/A2/N	Renal and urinary disorders/ Urinary retention/ URINARY RETENTION	05AUG2013 /63	11AUG2013 /26	I	1	2	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
304-0004/69 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	06AUG2013 /64	25SEP2013 /71	C	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Decubitus ulcer/ BED SORE AT SACRUM	10AUG2013 /68	25SEP2013 /71	C	1	1	1	5	2
	Infections and infestations/ Liver abscess/ LIVER ABSCESS	07AUG2013 /65	25SEP2013 /71	C	1	1	1	5	3
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	02AUG2013 /60	25SEP2013 /71	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
304-0004/69 /M/A2/N	Infections and infestations/ Peritonitis/ PERITONITIS	28JUL2013 /55	15AUG2013 /30	C	1	1	1	5	3
	General disorders and administration site conditions/ Pyrexia/ FEVER	23JUL2013 /50	23JUL2013 /7	I	1	0	1	5	1
	Gastrointestinal disorders/ Constipation/ WORSENING OF CONSTIPATION	06JUL2013 /33	25SEP2013 /71	C	1	1	1	5	3
	Gastrointestinal disorders/ Ascites/ WORSENING OF ASCITES	10JUL2013 /37	25SEP2013 /71	C	1	3	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
304-0004/69 /M/A2/N	Gastrointestinal disorders/ Gastric ulcer/ GASTRIC ULCER	09JUL2013 /36	25SEP2013 /71	C	1	1	1	5	2
	General disorders and administration site conditions/ Oedema/ PITTING EDEMA	08JUL2013 /35	10SEP2013 /56	I	1	1	1	5	1
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	01JUL2013 /28	28JUL2013 /12	C	1	1	1	5	2
	Gastrointestinal disorders/ Erosive duodenitis/ DUODENAL EROSIONS	09JUL2013 /36	25SEP2013 /71	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
304-0004/69 /M/A2/N	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	01JUL2013 /28	25SEP2013 /71	C	1	1	1	5	3
	Respiratory, thoracic and mediastinal disorders/ Hiccups/ HICCUP	29JUN2013 /26	30JUN2013 /-16	I	1	1	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ WORSENING OF ANOREXIA	27JUN2013 /24	29JUL2013 /13	I	1	1	1	5	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	07JUL2013 /34	28JUL2013 /12	C	1	2	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
304-0004/69 /M/A2/N	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	25JUN2013 /22	01JUL2013 /-15	C	1	1	3 /25JUN2013 /05JUL2013	5	3
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	11JUN2013 /8	25JUN2013 /-21	C	1	1	1	5	2
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	11JUN2013 /8	25JUN2013 /-21	C	1	0	1	5	3
	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	11JUN2013 /8	25JUN2013 /-21	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
304-0004/69 /M/A2/N	Metabolism and nutrition disorders/ Hypophosphataemia/ HYPOPHOSPHATEMIA	11JUN2013 /8	25JUN2013 /-21	C	1	0	1	5	2
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	09JUN2013 /6	02JUL2013 /-14	I	1	1	1	5	1
	Gastrointestinal disorders/ Gastrooesophageal reflux disease/ REFLUX ESOPHAGITIS	09JUL2013 /36	25SEP2013 /71	C	1	1	1	5	2
	Infections and infestations/ Sepsis/ SEPSIS	28JUL2013 /55	07SEP2013 /53	I	1	1	1	5 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
304-0004/69 /M/A2/N	Infections and infestations/ Biliary tract infection/ BILIARY TRACT INFECTION	27JUN2013 /24	16JUL2013 /0	C	1	1	1	5[Hyperbili rubinemia,o bstructive Jaundice]	3
	Hepatobiliary disorders/ Jaundice cholestatic/ OBSTRUCTIVE JAUNDICE	25JUN2013 /22	16JUL2013 /0	C	1	2	3 /25JUN2013 /05JUL2013	5[CD]	3
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	14AUG2013 /72	25SEP2013 /71	C	1	0	1	5	2
	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	11JUN2013 /8	25JUN2013 /-21	C	1	0	3 /18JUN2013 /25JUN2013	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
304-0007/72 /M/A2/N	Vascular disorders/ Hypertension/ HYPERTENSION	13NOV2013 /0	28SEP2014 /249	C	1	1	1	5	2
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Tumour pain/ TUMOR PAIN	13NOV2013 /0	28SEP2014 /249	C	1	1	1	5	2
	Investigations/ Weight decreased/ WEIGHT LOSS	15JAN2014 /63	22JAN2014 /0	I	1	0	1	5	1
305-0004/79 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Acute respiratory failure/ ACUTE RESPIRATORY FAILURE	18MAY2012 /84	02JUN2012 /23	C	1	3	1	5	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0004/79 /M/A2/N	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	30MAY2012 /96	03JUL2012 /54	C	1	1	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	24MAY2012 /90	03JUL2012 /54	C	1	1	1	5	3
	Infections and infestations/ Sepsis/ SEPSIS	18MAY2012 /84	07JUN2012 /28	C	1	3	1	5	4
	Renal and urinary disorders/ Urinary retention/ URINARY RETENTION	21MAY2012 /87	03JUL2012 /54	C	1	3	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0004/79 /M/A2/N	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIS	19MAY2012 /85	03JUL2012 /54	C	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Lung infiltration/ INFILTRATION AT LUNG	22MAR2012 /27	29MAR2012 /-42	I	1	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea exertional/ DYSPEA ON EXERTION	09MAR2012 /14	18MAY2012 /8	I	1	0	1	4	1
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	15MAY2012 /81	24JUN2012 /45	I	1	3	2	5 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0004/79 /M/A2/N	Gastrointestinal disorders/ Upper gastrointestinal haemorrhage/ UPPER GASTROINTESTINAL HEMORRHAGE	18MAY2012 /84	04JUN2012 /25	C	1	2	1	5	3
	General disorders and administration site conditions/ Pyrexia/ FEVER	19MAY2012 /85	03JUL2012 /54	I	1	1	1	5	1
305-0007/67 /M/A2/N	Cardiac disorders/ Palpitations/ PALPITATION	28JUL2012 /141	07SEP2012 /21	I	1	0	1	5	1
	Investigations/ Weight decreased/ WEIGHT LOSS	14SEP2012 /189	08NOV2013 /448	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0007/67 /M/A2/N	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	10AUG2012 /154	08NOV2013 /448	I	1	0	1	5	1
	Hepatobiliary disorders/ Hepatomegaly/ HEPATOMEGALY	22JUN2012 /105	08NOV2013 /448	C	1	0	1	5	1
	Renal and urinary disorders/ Nocturia/ NOCTURIA	07JUL2012 /120	16AUG2012 /-1	I	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ MILD RIGHT UPPER QUADRANT DISCOMFORT	07JUL2012 /120	19JUL2012 /-29	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0007/67 /M/A2/N	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	06JUL2012 /119	19JUL2012 /-29	C	1	1	1	3	1
	Metabolism and nutrition disorders/ Hypocalcaemia/ HYPOCALCEMIA	22JUN2012 /105	05JUL2012 /-43	C	1	0	1	5	1
	Investigations/ Neutrophil count decreased/ NEUTROPHIL COUNT DECREASED	22JUN2012 /105	08NOV2013 /448	C	1	0	1	5	2
	Metabolism and nutrition disorders/ Hypocalcaemia/ HYPOCALCEMIA	25MAY2012 /77	07JUN2012 /-71	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0007/67 /M/A2/N	Investigations/ Neutrophil count decreased/ NEUTROPHIL COUNT DECREASED	16MAR2012 /7	10MAY2012 /-99	C	1	0	1	5	2
	Metabolism and nutrition disorders/ Hypercalcaemia/ HYPERCALCEMIA	11MAY2012 /63	24MAY2012 /-85	C	1	0	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	04MAY2012 /56	25MAY2012 /-84	I	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THOART	04MAY2012 /56	24MAY2012 /-85	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0007/67 /M/A2/N	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	04MAY2012 /56	24MAY2012 /-85	C	1	1	1	5	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	30MAR2012 /21	18MAY2012 /-91	I	1	0	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	10MAR2012 /1	10MAR2012 /-160	I	1	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FAITGUE	14APR2012 /36	08NOV2013 /448	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0007/67 /M/A2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	08SEP2012 /183	10SEP2012 /24	C	1	0	1	5	1
305-0015/84 /M/A2/Y	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	19JUL2012 /13	02AUG2012 /-42	C	1	1	1	4[CD]	3
	Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	18OCT2012 /104	01NOV2012 /49	I	1	0	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	02OCT2012 /88	02OCT2012 /19	I	2	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0015/84 /M/A2/Y	Gastrointestinal disorders/ Pancreatitis acute/ ACUTE PANCREATITIS	24SEP2012 /80	06OCT2012 /23	C	1	1	1	4 [PD]	3
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	19JUL2012 /13	01AUG2012 /-43	I	1	0	1	4	1
	Psychiatric disorders/ Delirium/ DELIRIUM	01OCT2012 /87	03OCT2012 /20	C	1	1	1	5	3
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	03SEP2012 /59	03SEP2012 /-10	I	2	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0016/78 /M/A2/N	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	16AUG2012 /37	21AUG2012 /-42	C	1	0	1	5	2
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	25SEP2012 /77	28OCT2012 /26	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Hypoglycaemia/ HYPOGLYCEMIA	18AUG2012 /39	21AUG2012 /-42	I	1	1	1	5	1
	Metabolism and nutrition disorders/ Hypocalcaemia/ HYPOCALCEMIA	25SEP2012 /77	13OCT2012 /11	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0016/78 /M/A2/N	Investigations/ Blood creatinine increased/ CREATININE INCREASED	11SEP2012 /63	18OCT2012 /16	C	1	0	1	5	1
	Nervous system disorders/ Burning sensation/ LEFT THIGH BURNING	12SEP2012 /64	06OCT2012 /4	I	1	1	1	5	1
	Nervous system disorders/ Hypoaesthesia/ LEFT THIGH NUMBNESS	10SEP2012 /62	06OCT2012 /4	C	1	0	1	5	1
	General disorders and administration site conditions/ Injection site pruritus/ INJECTION SITE REACTION (ITCHING)	04SEP2012 /56	25SEP2012 /-7	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0016/78 /M/A2/N	Musculoskeletal and connective tissue disorders/ Flank pain/ LEFT FLANK PAIN	20AUG2012 /41	23AUG2012 /-40	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ MILD DYSPNEA SENSATION	20AUG2012 /41	21AUG2012 /-42	I	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ LEFT UPPER QUADRANT PAIN	20AUG2012 /41	23AUG2012 /-40	I	1	1	1	5	1
	Metabolism and nutrition disorders/ Hypocalcaemia/ HYPOCALCEMIA	28AUG2012 /49	11SEP2012 /-21	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0016/78 /M/A2/N	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	16AUG2012 /37	11SEP2012 /-21	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Hypophosphataemia/ HYPOPHOSPHATEMIA	14AUG2012 /35	11SEP2012 /-21	C	1	0	1	5	3
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	28AUG2012 /49	12OCT2012 /10	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	25AUG2012 /46	27AUG2012 /-36	C	1	2	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0016/78 /M/A2/N	Infections and infestations/ Oral candidiasis/ ORAL CANDIDIASIS	28AUG2012 /49	03SEP2012 /-29	C	1	1	1	5	1
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	22AUG2012 /43	28AUG2012 /-35	C	1	0	1	5	1
	Gastrointestinal disorders/ Ascites/ ASCITES	22AUG2012 /43	07OCT2012 /5	C	1	3	1	5	3
	Infections and infestations/ Klebsiella infection/ KLEB.PNEUMONIAE INFECTION	16AUG2012 /37	28AUG2012 /-35	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0016/78 /M/A2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	13AUG2012 /34	15AUG2012 /-48	I	1	1	1	5	1
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	15AUG2012 /36	27AUG2012 /-36	C	1	0	1	5	2
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	16AUG2012 /37	22AUG2012 /-41	C	1	0	1	5	3
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	01AUG2012 /22	14AUG2012 /-49	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0016/78 /M/A2/N	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH	08AUG2012 /29	16AUG2012 /-47	C	1	1	1	3	1
	General disorders and administration site conditions/ Chills/ CHILLS	16AUG2012 /37	18AUG2012 /-45	I	1	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	16AUG2012 /37	18AUG2012 /-45	I	1	1	1	5	2
	Infections and infestations/ Sepsis/ SEPSIS	16AUG2012 /37	29AUG2012 /-34	C	1	1	3 /21AUG2012 /28AUG2012	5 [CD]	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0016/78 /M/A2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	25JUL2012 /15	12NOV2012 /41	C	1	0	1	3	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	10JUL2012 /0	24JUL2012 /-70	C	1	0	1	5	1
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	01AUG2012 /22	14AUG2012 /-49	C	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	20AUG2012 /41	23AUG2012 /-40	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0016/78 /M/A2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	06OCT2012 /88	06OCT2012 /4	I	1	1	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	18OCT2012 /100	27OCT2012 /25	C	1	0	1	5	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	06OCT2012 /88	07OCT2012 /5	C	1	2	1	5	3
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	28AUG2012 /49	11SEP2012 /-21	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0016/78 /M/A2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	14OCT2012 /96	15OCT2012 /13	I	1	0	1	5	1
	Injury, poisoning and procedural complications/ Transfusion reaction/ BLOOD TRANSFUSION ADVERSE REACTION	06OCT2012 /88	06OCT2012 /4	C	1	1	1	5	1
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	13OCT2012 /95	12NOV2012 /41	C	1	0	1	5	3
	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	16AUG2012 /37	17AUG2012 /-46	C	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0016/78 /M/A2/N	Gastrointestinal disorders/ Abdominal pain/ RIGHT SIDE ABDOMINAL PAIN	06OCT2012 /88	12NOV2012 /41	C	1	1	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	13OCT2012 /95	12NOV2012 /41	C	1	0	1	5	2
	Metabolism and nutrition disorders/ Hypoglycaemia/ HYPOGLYCEMIA	21OCT2012 /103	21OCT2012 /19	I	1	1	1	5	1
	Psychiatric disorders/ Agitation/ AGITATION	12OCT2012 /94	12NOV2012 /41	C	1	3	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0016/78 /M/A2/N	General disorders and administration site conditions/ Chills/ CHILLS	06OCT2012 /88	06OCT2012 /4	I	1	0	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	30SEP2012 /82	12NOV2012 /41	I	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ STOMACH PAIN	11OCT2012 /93	12OCT2012 /10	I	1	1	1	5	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	01OCT2012 /83	12NOV2012 /41	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0016/78 /M/A2/N	Injury, poisoning and procedural complications/ Scratch/ SCROTUM SCRATCHD	27OCT2012 /109	12NOV2012 /41	C	1	1	1	5	1
	Investigations/ Blood creatinine increased/ CREATININE INCREASED	05NOV2012 /118	12NOV2012 /41	C	1	0	1	5	3
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	11OCT2012 /93	17OCT2012 /15	C	1	2	1	5	3
	Investigations/ Blood creatinine increased/ CREATININE INCREASED	28OCT2012 /110	04NOV2012 /33	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0016/78 /M/A2/N	Renal and urinary disorders/ Haematuria/ HEMATURIA	22OCT2012 /104	12NOV2012 /41	C	1	1	1	5	3
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	06OCT2012 /88	12NOV2012 /41	C	4	1	2	5 [CD]	3
	Metabolism and nutrition disorders/ Hypoglycaemia/ HYPOGLYCEMIA	30SEP2012 /82	30SEP2012 /-2	C	1	1	1	5 [CM]	3
	Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORE THROAT	08OCT2012 /90	09OCT2012 /7	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0016/78 /M/A2/N	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	08OCT2012 /90	31OCT2012 /29	C	1	0	1	5	1
	Gastrointestinal disorders/ Ascites/ ASCITES	08OCT2012 /90	12NOV2012 /41	C	1	1	1	5	2
	Infections and infestations/ Abdominal infection/ ABDOMINAL INFECTION	06OCT2012 /88	12NOV2012 /41	C	1	1	1	5	3
	Investigations/ Blood creatinine increased/ CREATININE INCREASED	23OCT2012 /105	28OCT2012 /26	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0016/78 /M/A2/N	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	28OCT2012 /110	05NOV2012 /34	C	1	1	1	5	3
305-0021/83 /F/A2/N	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	25DEC2012 /33	08JAN2013 /-28	C	1	3	1	4	3
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	25DEC2012 /33	28DEC2012 /-39	C	1	1	1	4	1
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	15FEB2013 /85	23MAR2013 /46	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0021/83 /F/A2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	15FEB2013 /85	23MAR2013 /46	I	1	0	1	4	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	05FEB2013 /75	Unknown/NA	C	6	2	1	4	2
305-0024/69 /M/A2/Y	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS	02MAR2013 /46	22MAR2013 /-12	I	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRAGIA	16MAR2013 /60	29MAR2013 /-5	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0024/69 /M/A2/Y	General disorders and administration site conditions/ Fatigue/ FATIGUE	16FEB2013 /32	Unknown/NA	C	6	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	02FEB2013 /18	22FEB2013 /-40	I	1	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	16JAN2013 /1	01FEB2013 /-61	C	1	0	1	3	1
305-0033/37 /F/A2/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	16SEP2013 /76	16SEP2013 /-1	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0033/37 /F/A2/Y	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	11SEP2013 /71	19JUL2014 /305	I	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	21AUG2013 /50	02SEP2013 /-15	I	1	1	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	30JUL2013 /28	01AUG2013 /-47	I	1	0	1	3	1
	Metabolism and nutrition disorders/ Hypouricaemia/ HYPOURICEMIA	30JUL2013 /28	06AUG2013 /-42	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0033/37 /F/A2/Y	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	23JUL2013 /21	19JUL2014 /305	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Hypouricaemia/ HYPOURICEMIA	16JUL2013 /14	22JUL2013 /-57	C	1	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	15JUL2013 /13	17JUL2013 /-62	I	1	1	1	3	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	03JUL2013 /1	Unknown/NA	I	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0033/37 /F/A2/Y	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ SHOULDER PAIN	02JUL2013 /0	19JUL2014 /305	I	1	1	1	5	1
	Gastrointestinal disorders/ Gastroesophageal reflux disease/ REFLUX ESOPHAGITIS	02JUL2013 /0	19JUL2014 /305	C	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRAGIA	21AUG2013 /50	02SEP2013 /-15	I	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Myalgia/ MUSCLE SORENESS	24JUL2013 /22	19JUL2014 /305	I	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0035/60 /M/A2/Y	Renal and urinary disorders/ Chromaturia/ URINE DISCOLORATION	17JAN2014 /142	27JAN2014 /-9	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	28JAN2014 /153	12FEB2014 /7	I	1	0	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	05FEB2014 /161	29SEP2014 /236	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	02OCT2013 /35	16OCT2013 /-112	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0035/60 /M/A2/Y	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	25DEC2013 /119	22JAN2014 /-14	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	01JAN2014 /126	17JAN2014 /-19	I	1	1	1	5	1
	Nervous system disorders/ Hypoaesthesia/ ACID REGITATION	19DEC2013 /113	12FEB2014 /7	I	1	1	1	3	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	03OCT2013 /36	12FEB2014 /7	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0035/60 /M/A2/Y	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH	04DEC2013 /98	11DEC2013 /-56	I	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	24OCT2013 /57	13NOV2013 /-84	I	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN ITCHING	17OCT2013 /50	30OCT2013 /-98	C	1	0	1	5	1
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	02OCT2013 /35	13NOV2013 /-84	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0035/60 /M/A2/Y	Renal and urinary disorders/ Chromaturia/ URINE DISCOLORATION	19SEP2013 /22	16OCT2013 /-112	I	1	0	1	5	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	29AUG2013 /1	25SEP2013 /-133	I	1	0	1	3	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	24OCT2013 /57	13NOV2013 /-84	I	1	0	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	30OCT2013 /63	11DEC2013 /-56	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
305-0035/60 /M/A2/Y	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	28JAN2014 /153	29SEP2014 /236	I	1	0	1	5	1
305-0046/60 /M/A2/Y	Gastrointestinal disorders/ Vomiting/ VOMITING	11MAY2015 /185	12MAY2015 /28	I	1	1	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	11MAY2015 /185	12MAY2015 /28	I	1	1	1	5	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	10FEB2015 /95	17FEB2015 /-56	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0004/46 /M/A2/Y	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	06APR2012 /45	07APR2012 /11	C	1	1	1	5	3
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	02APR2012 /41	05APR2012 /9	C	1	1	1	5	3
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	26MAR2012 /34	02APR2012 /6	C	1	1	1	5	2
	Skin and subcutaneous tissue disorders/ Rash/ GENERAL SKIN RASH	03APR2012 /42	04APR2012 /8	C	1	1	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0004/46 /M/A2/Y	Skin and subcutaneous tissue disorders/ Rash/ GENERAL SKIN RASH	29MAR2012 /37	03APR2012 /7	C	1	1	3 /29MAR2012 /Unknown	2	3
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	06MAR2012 /14	13MAR2012 /-14	I	1	0	1	5	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	23MAR2012 /31	07APR2012 /11	C	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	24MAR2012 /32	07APR2012 /11	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0004/46 /M/A2/Y	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	22MAR2012 /30	24MAR2012 /-3	C	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMEN FULLNESS	23MAR2012 /31	03APR2012 /7	I	1	1	1	5	1
	Investigations/ Weight decreased/ BODY WEIGHT LOSS	06MAR2012 /14	13MAR2012 /-14	C	1	0	1	5	1
	Infections and infestations/ Biliary tract infection/ BILIARY TRACT INFECTION	21MAR2012 /29	07APR2012 /11	C	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0004/46 /M/A2/Y	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	13MAR2012 /21	07APR2012 /11	C	1	0	1	4	3
	Gastrointestinal disorders/ Vomiting/ VOMITING	21MAR2012 /29	24MAR2012 /-3	I	1	1	1	5	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	21MAR2012 /29	24MAR2012 /-3	I	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Flank pain/ RIGHT FLANK PAIN	06MAR2012 /14	13MAR2012 /-14	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0004/46 /M/A2/Y	General disorders and administration site conditions/ Oedema peripheral/ LOWER LEG EDEMA	26MAR2012 /34	06APR2012 /10	I	1	1	1	5	1
	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINEMIA	21MAR2012 /29	07APR2012 /11	C	1	1	1	5 [PD]	3
	Gastrointestinal disorders/ Vomiting/ VOMITING	28FEB2012 /7	29FEB2012 /-27	C	1	0	1	5	1
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	13MAR2012 /21	07APR2012 /11	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0004/46 /M/A2/Y	Gastrointestinal disorders/ Ascites/ ASCITES	20MAR2012 /28	07APR2012 /11	C	1	1	1	4	1
	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	07APR2012 /46	07APR2012 /11	C	1	1	1	5	4
	Blood and lymphatic system disorders/ Normochromic normocytic anaemia/ NORMOCYTIC ANEMIA	06APR2012 /45	07APR2012 /11	C	1	2	1	5	2
	Blood and lymphatic system disorders/ Coagulopathy/ COAGULOPATHY	26MAR2012 /34	07APR2012 /11	C	1	2	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0004/46 /M/A2/Y	Skin and subcutaneous tissue disorders/ Palmar erythema/ BOTH PALMAR ERYTHEMA	27MAR2012 /35	07APR2012 /11	C	1	0	1	5	1
	Blood and lymphatic system disorders/ Leukocytosis/ LEUKOCYTOSIS	06APR2012 /45	07APR2012 /11	C	1	1	1	5	2
	Gastrointestinal disorders/ Oesophageal varices haemorrhage/ ESOPHAGEAL VARICES BLEEDING	06APR2012 /45	07APR2012 /11	C	1	1	1	5	1
	Hepatobiliary disorders/ Hyperbilirubinaemia/ HYPERBILIRUBINEMIA	13MAR2012 /21	21MAR2012 /-6	C	1	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0004/46 /M/A2/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to lung/ LUNG METASTASIS	03APR2012 /42	07APR2012 /11	C	1	0	1	5	3
	Gastrointestinal disorders/ Vomiting/ VOMITING	06APR2012 /45	07APR2012 /11	I	1	1	1	5	2
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	06APR2012 /45	07APR2012 /11	C	1	1	1	5	2
	Vascular disorders/ Hypotension/ HYPOTENSION	06APR2012 /45	07APR2012 /11	C	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0004/46 /M/A2/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	28FEB2012 /7	29FEB2012 /-27	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Metabolic acidosis/ METABOLIC ACIDOSIS	07APR2012 /46	07APR2012 /11	C	1	1	1	5	3
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	06APR2012 /45	07APR2012 /11	C	4	1	1	5 [PD]	5
306-0010/69 /M/A2/N	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	24JUN2012 /95	30MAR2013 /297	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0010/69 /M/A2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	15MAY2012 /55	07JUN2012 /1	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Epistaxis/ EPISTAXIS	04JUL2012 /105	04JUL2012 /28	I	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ LEFT SHOULDER SORENESS	27JUN2012 /98	30MAR2013 /297	I	1	2	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	24JUN2012 /95	30JUN2012 /24	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0010/69 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	17APR2012 /27	26APR2012 /-41	C	1	1	1	5	1
	Ear and labyrinth disorders/ Tinnitus/ RIGHT TINNITUS	20JUN2012 /91	30MAR2013 /297	I	1	3	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Epistaxis/ RIGHT NASAL BLEEDING	18JUN2012 /89	18JUN2012 /12	I	1	1	1	5	2
	Skin and subcutaneous tissue disorders/ Pruritus generalised/ GENERALIZED SKIN ITCHING	04MAY2012 /44	25JUN2012 /19	C	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0010/69 /M/A2/N	Musculoskeletal and connective tissue disorders/ Bone pain/ GENERALIZED BONE SORENESS	17APR2012 /27	26APR2012 /-41	C	1	1	1	5	1
	Metabolism and nutrition disorders/ Gout/ GOUT	03MAY2012 /43	30MAR2013 /297	C	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	11APR2012 /21	16APR2012 /-51	I	6	1	1	5	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMEN FULLNESS	26APR2012 /36	08MAY2012 /-29	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0010/69 /M/A2/N	Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIA	19APR2012 /29	25APR2012 /-42	C	1	1	1	5	3
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	27APR2012 /37	14MAY2012 /-23	I	1	1	1	5	1
	Gastrointestinal disorders/ Gastric ulcer/ GASTRIC ULCER	19APR2012 /29	30MAR2013 /297	C	1	1	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	18APR2012 /28	19APR2012 /-48	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0010/69 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	17APR2012 /27	26APR2012 /-41	I	2	1	3 /17APR2012 /25APR2012	5	3
	Gastrointestinal disorders/ Gastrointestinal haemorrhage/ HEMORRHAGE OF GASTROINTESTINAL	19APR2012 /29	20APR2012 /-47	C	1	3	1	5 [PD]	3
	Infections and infestations/ Pneumonia/ PNEUMONIA	17APR2012 /27	26APR2012 /-41	C	1	1	3 /17APR2012 /25APR2012	5 [PD]	3
	General disorders and administration site conditions/ Pyrexia/ FEVER	12APR2012 /22	19APR2012 /-48	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0010/69 /M/A2/N	Gastrointestinal disorders/ Nausea/ NAUSEA	21MAR2012 /0	28MAR2012 /-70	C	1	1	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	21MAR2012 /0	28MAR2012 /-70	C	1	1	1	5	1
306-0013/42 /M/A2/Y	General disorders and administration site conditions/ Medical device complication/ DRAINAGE TUBE OBSTRUCTION	20MAY2012 /34	20MAY2012 /-22	I	1	3	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ LEFT PLEURAL EFFUSION	11JUN2012 /56	18JUN2012 /7	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0013/42 /M/A2/Y	General disorders and administration site conditions/ Malaise/ MALAISE	24APR2012 /8	18JUN2012 /7	C	1	0	1	5	1
	Cardiac disorders/ Sinus tachycardia/ SINUS TACHYCARDIA(WORSENING)	14MAY2012 /28	18JUN2012 /7	C	1	1	1	5	2
	Gastrointestinal disorders/ Dyspepsia/ DYSPEPSIA(VOMITING AND NEUSEA)	10JUN2012 /55	18JUN2012 /7	I	1	1	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA(POOR APPETITE)	10JUN2012 /55	18JUN2012 /7	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0013/42 /M/A2/Y	Musculoskeletal and connective tissue disorders/ Pain in extremity/ PAIN IN EXTREMITY(RIGHT LOWER LIMB PAIN)	15JUN2012 /60	18JUN2012 /7	I	1	3	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	07MAY2012 /21	13MAY2012 /-29	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	10JUN2012 /55	18JUN2012 /7	I	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	04JUN2012 /49	18JUN2012 /7	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0013/42 /M/A2/Y	General disorders and administration site conditions/ Disease progression/ MALIGNANT DISEASE OF HEPATOCELLULAR CARCINOMA WORSENING	10JUN2012 /55	18JUN2012 /7	C	4	0	1	5 [PD]	3
	Gastrointestinal disorders/ Abdominal distension/ BLOATING (ABDOMINAL FULLNESS)	10JUN2012 /55	18JUN2012 /7	C	1	0	1	5	2
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS (BILATERAL LEGS EDEMA)	24MAY2012 /38	18JUN2012 /7	C	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT PAIN	11JUN2012 /56	18JUN2012 /7	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0013/42 /M/A2/Y	General disorders and administration site conditions/ Pyrexia/ FEVER	05JUN2012 /50	05JUN2012 /-6	I	1	1	1	5	1
	Gastrointestinal disorders/ Ascites/ ASCITES	11JUN2012 /56	18JUN2012 /7	C	1	1	1	5	2
	Gastrointestinal disorders/ Abdominal distension/ BLOATING (ABDOMINAL FULLNESS)	07MAY2012 /21	27MAY2012 /-15	I	1	1	1	5	1
306-0015/73 /M/A2/N	Gastrointestinal disorders/ Abdominal distension/ BLOATING (RIGHT UPPER QUADRANT )	07JUN2012 /21	14JUN2012 /-7	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0015/73 /M/A2/N	Gastrointestinal disorders/ Abdominal pain upper/ ABDOMINAL PAIN (RIGHT UPPER QUADRANT)	15JUN2012 /29	20JUL2012 /29	I	1	0	1	5	1
	Investigations/ Alpha 1 foetoprotein increased/ ALPHA-FETOPROTEIN INCREASED	08JUN2012 /22	14MAY2013 /327	C	1	0	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA LIMBS (LOWER LEGS)	07JUN2012 /21	20JUL2012 /29	C	1	0	1	5	1
306-0016/58 /M/A2/Y	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	11SEP2012 /78	21SEP2013 /375	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0016/58 /M/A2/Y	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS (SKIN ITCHING)	25JUN2012 /0	05JUL2012 /-68	I	1	0	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	07SEP2012 /74	17SEP2012 /6	I	1	1	1	5	2
	Investigations/ White blood cell count increased/ WHITE BLOOD CELL INCREASED	13AUG2012 /49	27AUG2012 /-15	C	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Wheezing/ WHEEZING	10AUG2012 /46	26AUG2012 /-16	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0016/58 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	10AUG2012 /46	26AUG2012 /-16	I	1	1	1	5	2
306-0022/56 /M/A2/N	Gastrointestinal disorders/ Abdominal pain upper/ RIGHT UPPER QUADRANT PAIN	25DEC2012 /42	02JAN2013 /-111	I	1	0	1	4	1
	Musculoskeletal and connective tissue disorders/ Bone pain/ BONE SORENESS	20NOV2012 /7	27NOV2012 /-147	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Lung infiltration/ LUNG INFILTRATION	18DEC2012 /35	02JAN2013 /-111	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0022/56 /M/A2/N	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	23APR2013 /161	03FEB2014 /286	C	1	0	1	4	1
	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	26MAR2013 /133	03FEB2014 /286	I	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Flank pain/ RIGHT FLANK PAIN	19MAR2013 /126	03FEB2014 /286	I	1	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	27NOV2012 /14	04DEC2012 /-140	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0022/56 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	12MAR2013 /119	30APR2013 /7	I	1	0	1	4	1
	Injury, poisoning and procedural complications/ Procedural complication/ GENERALIZED SKIN RASH (DUE TO NEW PROCEDURE SIDE EFFECT)	21MAY2013 /189	03FEB2014 /286	C	1	1	1	5	2
	Nervous system disorders/ Dizziness/ DIZZINESS	08JAN2013 /56	15JAN2013 /-98	I	1	0	1	4	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	27NOV2012 /14	04DEC2012 /-140	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0022/56 /M/A2/N	Infections and infestations/ Carbuncle/ RIGHT EYE CARBUNCLE	02JAN2013 /50	15JAN2013 /-98	C	1	0	1	4	1
306-0028/53 /M/A2/N	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	13JUN2013 /77	04JUL2013 /31	I	1	0	1	5	1
306-0045/60 /F/A1/N	Psychiatric disorders/ Anxiety/ ANXIETY	08JUL2014 /18	19AUG2014 /-14	I	1	0	1	4	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	10SEP2014 /82	12JUN2015 /283	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
306-0045/60 /F/A1/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	23SEP2014 /95	12DEC2014 /101	C	1	1	1	4	2
	Investigations/ Weight decreased/ WEIGHT LOSS	02SEP2014 /74	03OCT2014 /31	C	1	0	1	4	1
	Vascular disorders/ Hypotension/ HYPOTENSION	26AUG2014 /67	09SEP2014 /7	I	1	0	1	4	1
	Nervous system disorders/ Dizziness/ DIZZINESS	10SEP2014 /82	03OCT2014 /31	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0006/72 /M/A2/N	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	06DEC2011 /7	19DEC2011 /13	C	1	0	1	5	2
	Gastrointestinal disorders/ Dysphagia/ DYSPHAGIA	19DEC2011 /20	23DEC2011 /17	C	1	0	1	5	3
	General disorders and administration site conditions/ Pain/ WHOLE BODY PAIN	19DEC2011 /20	23DEC2011 /17	C	1	1	1	5	3
	Psychiatric disorders/ Agitation/ AGITATION	19DEC2011 /20	23DEC2011 /17	I	1	3	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0006/72 /M/A2/N	Nervous system disorders/ Depressed level of consciousness/ CONSCIOUS DROWSY	19DEC2011 /20	23DEC2011 /17	I	1	0	1	5	2
	Blood and lymphatic system disorders/ Leukocytosis/ LEUKOCYTOSIS	12DEC2011 /13	23DEC2011 /17	C	1	1	1	5	2
	Gastrointestinal disorders/ Ascites/ ASCITES	13DEC2011 /14	23DEC2011 /17	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	13DEC2011 /14	23DEC2011 /17	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0006/72 /M/A2/N	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	06DEC2011 /7	23DEC2011 /17	C	1	0	1	5	2
	Investigations/ Protein total decreased/ DECREASED TOTAL PROTERIN	06DEC2011 /7	23DEC2011 /17	C	1	0	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	06DEC2011 /7	23DEC2011 /17	I	1	2	1	5	2
	Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	19DEC2011 /20	23DEC2011 /17	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0006/72 /M/A2/N	General disorders and administration site conditions/ Oedema peripheral/ WORSENING OF EDEMA LIMBS	12DEC2011 /13	23DEC2011 /17	C	1	1	1	5	3
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	01DEC2011 /2	23DEC2011 /17	I	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	19DEC2011 /20	23DEC2011 /17	C	1	2	1	5	3
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	05DEC2011 /6	19DEC2011 /13	C	1	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0006/72 /M/A2/N	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	19DEC2011 /20	23DEC2011 /17	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	19DEC2011 /20	19DEC2011 /13	C	1	1	1	5	3
	Hepatobiliary disorders/ Hepatic failure/ HEPATIC FAILURE	19DEC2011 /20	23DEC2011 /17	C	4	0	2	5 [PD]	4
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	12DEC2011 /13	19DEC2011 /13	C	1	0	3 /13DEC2011 /Unknown	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0006/72 /M/A2/N	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	06DEC2011 /7	12DEC2011 /6	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ WORSENING OF ANOREXIA	19DEC2011 /20	23DEC2011 /17	C	1	1	1	5	3
	General disorders and administration site conditions/ Fatigue/ WORSENING OF FATIGUE	19DEC2011 /20	23DEC2011 /17	C	1	0	1	5	3
	Gastrointestinal disorders/ Nausea/ NAUSEA	29NOV2011 /0	19DEC2011 /13	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0006/72 /M/A2/N	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	19DEC2011 /20	23DEC2011 /17	C	1	0	1	5 [PD]	4
307-0009/53 /M/A2/N	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	17JAN2012 /14	29MAR2012 /62	C	1	1	1	5	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	03JAN2012 /0	29MAR2012 /62	C	1	1	1	5	1
	Hepatobiliary disorders/ Hepatic failure/ HEPATIC FAILURE	03FEB2012 /31	17FEB2012 /21	C	1	1	2	5 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0009/53 /M/A2/N	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	27JAN2012 /24	29MAR2012 /62	C	1	0	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	27JAN2012 /24	01FEB2012 /5	C	1	1	1	5[Cause Unknown]	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	17JAN2012 /14	29MAR2012 /62	C	1	0	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	10JAN2012 /7	29MAR2012 /62	C	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0012/42 /M/A2/N	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	29FEB2012 /22	07MAR2012 /29	C	1	0	1	5	2
	Cardiac disorders/ Supraventricular tachycardia/ PAROXYSMAL SUPRAVENTRICULAR TACHYCARDIA	27FEB2012 /20	27FEB2012 /20	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	23FEB2012 /16	27FEB2012 /20	C	1	1	1	5	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	21FEB2012 /14	29FEB2012 /22	C	1	2	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0012/42 /M/A2/N	Nervous system disorders/ Depressed level of consciousness/ CONSCIOUS DROWSY	21FEB2012 /14	24FEB2012 /17	C	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	21FEB2012 /14	08MAR2012 /30	C	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	21FEB2012 /14	28FEB2012 /21	C	1	2	1	5	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	16FEB2012 /9	10APR2012 /63	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0012/42 /M/A2/N	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	07FEB2012 /0	01MAR2012 /23	I	1	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	14FEB2012 /7	14FEB2012 /7	C	1	1	3 /14FEB2012 /Unknown	5	2
	Infections and infestations/ Infection/ INFECTION	18FEB2012 /11	01MAR2012 /23	C	1	1	1	5[Cause Unknown]	3
	General disorders and administration site conditions/ Malaise/ WORSENING OF GENERAL MALAISE	21FEB2012 /14	01MAR2012 /23	C	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0015/75 /M/A2/N	Vascular disorders/ Hypertension/ HYPERTENSION	01NOV2012 /190	05MAR2013 /152	C	1	1	1	5	2
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH (GENERAL)	01NOV2012 /190	17JAN2013 /105	C	1	1	1	5	1
	General disorders and administration site conditions/ Chest discomfort/ NOT OTHERWISE SPECIFIED CHEST DISCOMFORT	01NOV2012 /190	17JAN2013 /105	C	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Palmar-plantar erythrodysaesthesia syndrome/ HAND-FOOT SYNDROME	01NOV2012 /190	17JAN2013 /105	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0015/75 /M/A2/N	Musculoskeletal and connective tissue disorders/ Arthralgia/ BILATERAL KNEE JOINTS TENDERNESS	31MAY2012 /36	14FEB2013 /133	C	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	31MAY2012 /36	05MAR2013 /152	I	1	1	1	5	1
	Infections and infestations/ Fungal skin infection/ FUNGAL SKIN INFECTION(INGUINAL)	20SEP2012 /148	04OCT2012 /0	C	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	18JUL2012 /84	05MAR2013 /152	C	1	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0015/75 /M/A2/N	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH (ABDOMEN)	28JUN2012 /64	11OCT2012 /7	C	1	1	1	4	1
307-0021/68 /M/A2/N	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	03JAN2013 /135	09JAN2013 /20	C	1	2	1	5	3
	Gastrointestinal disorders/ Gastrointestinal haemorrhage/ GASTROINTESTINAL BLEEDING	03JAN2013 /135	08JAN2013 /19	I	1	3	1	5	3
	General disorders and administration site conditions/ Disease progression/ WORSENING OF HEPATOCELLULAR CARCINOMA	03JAN2013 /135	09JAN2013 /20	C	3	1	1	5 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0021/68 /M/A2/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	20DEC2012 /121	01FEB2013 /43	I	1	1	1	5	1
	General disorders and administration site conditions/ Oedema/ WORSENING OF BILATERAL PITTING EDEMA	06DEC2012 /107	10FEB2013 /52	I	1	1	1	5	2
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	06DEC2012 /107	04JAN2013 /15	C	1	1	1	4	1
	Gastrointestinal disorders/ Ascites/ WORSENING OF ASCITES	04DEC2012 /105	10FEB2013 /52	C	1	3	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0021/68 /M/A2/N	General disorders and administration site conditions/ Pain/ GENERAL SORENESS	22NOV2012 /93	04JAN2013 /15	C	1	1	1	4	1
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH (GENERAL)	08NOV2012 /79	04JAN2013 /15	C	1	1	1	3	1
	General disorders and administration site conditions/ Chest discomfort/ NOT OTHERWISE SPECIFIED CHEST TIGHTNESS	30AUG2012 /9	25OCT2012 /-56	I	1	0	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	06DEC2012 /107	20DEC2012 /0	C	1	2	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0021/68 /M/A2/N	Gastrointestinal disorders/ Abdominal pain/ WORSENING OF ABDOMINAL PAIN	25OCT2012 /65	10FEB2013 /52	C	1	1	1	5	2
307-0028/69 /F/A2/Y	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	18FEB2013 /35	15JUN2013 /75	C	1	1	1	5	3
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	18FEB2013 /35	15JUN2013 /75	C	1	1	1	5	2
	Skin and subcutaneous tissue disorders/ Alopecia/ ALOPECIA	04MAR2013 /49	18MAR2013 /-14	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0028/69 /F/A2/Y	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	24JAN2013 /10	18FEB2013 /-42	C	1	1	1	5	2
307-0034/48 /M/A2/N	General disorders and administration site conditions/ Malaise/ GENERAL MALAISE	03SEP2013 /21	24SEP2013 /-35	I	1	0	1	5	1
	Psychiatric disorders/ Insomnia/ INSOMNIA	20AUG2013 /7	04FEB2014 /98	C	1	1	1	5	1
	General disorders and administration site conditions/ Injection site rash/ SKIN RASH(INJECTION SITE)	22OCT2013 /70	28NOV2013 /30	I	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0034/48 /M/A2/N	General disorders and administration site conditions/ Pyrexia/ INTERMITTENT FEVER	18SEP2013 /36	04FEB2014 /98	I	1	1	1	4	1
	General disorders and administration site conditions/ Pain/ GENERAL SORENESS	01OCT2013 /49	28NOV2013 /30	I	1	0	1	3	1
307-0036/76 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	21JAN2014 /111	30JUN2014 /194	I	1	1	1	5	2
	Nervous system disorders/ Dizziness/ DIZZINESS	08OCT2013 /6	30JUN2014 /194	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0042/55 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	15NOV2014 /149	25FEB2015 /104	C	1	1	1	5	2
	Skin and subcutaneous tissue disorders/ Dry skin/ DRY SKIN	18DEC2014 /182	15JAN2015 /63	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ HYMOTYSIS	20NOV2014 /154	25FEB2015 /104	I	1	1	1	5	1
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH	18DEC2014 /182	15JAN2015 /63	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0042/55 /M/A2/Y	Infections and infestations/ Tinea cruris/ TINEA CRUIS	11SEP2014 /84	06NOV2014 /-7	C	1	1	1	5	1
	Gastrointestinal disorders/ Mouth ulceration/ ORAL ULCER	19JUN2014 /0	03JUL2014 /-133	C	1	1	1	5	2
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH	18DEC2014 /182	15JAN2015 /63	C	1	1	1	5	2
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH	27NOV2014 /161	17DEC2014 /34	C	2	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0042/55 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Pulmonary haemorrhage/ BRONCHOPULMONARY HEMORRHAGE	15NOV2014 /149	19NOV2014 /6	C	2	1	3 /18NOV2014 /Unknown	4 [CD]	3
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH	13NOV2014 /147	26NOV2014 /13	C	2	1	1	3	2
	Gastrointestinal disorders/ Mouth ulceration/ ORAL ULCER	06NOV2014 /140	18DEC2014 /35	C	1	1	1	4	1
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	24JUL2014 /35	06NOV2014 /-7	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
307-0042/55 /M/A2/Y	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH	10JUL2014 /21	12NOV2014 /-1	C	1	1	1	3	1
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH	19JUN2014 /0	09JUL2014 /-127	C	1	1	1	5	2
308-0002/36 /F/A2/N	Gastrointestinal disorders/ Gastritis/ GASTRITIS	16APR2013 /106	13AUG2013 /147	C	1	1	1	5	2
	Vascular disorders/ Hypertension/ HYPERTENSION	04MAR2013 /63	16FEB2014 /334	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0002/36 /F/A2/N	Psychiatric disorders/ Insomnia/ INSOMNIA	05FEB2013 /36	12FEB2013 /-35	C	1	1	1	4	1
	Nervous system disorders/ Headache/ HEADACHE	22JAN2013 /22	28JAN2013 /-50	C	1	1	1	4	1
	General disorders and administration site conditions/ Injection site reaction/ INJECTION SITE REACTION	08JAN2013 /8	23APR2013 /35	C	1	0	1	1	2
	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPRIRATORY INFECTION	07JAN2013 /7	16FEB2014 /334	C	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0002/36 /F/A2/N	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	07JAN2013 /7	16FEB2014 /334	C	1	1	1	4	2
308-0004/52 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	26MAR2013 /49	07APR2015 /714	I	1	1	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITTING	05MAR2013 /28	07APR2015 /714	I	1	0	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	05MAR2013 /28	07APR2015 /714	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0004/52 /M/A2/Y	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	26FEB2013 /21	07APR2015 /714	I	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	12MAR2013 /35	07APR2015 /714	C	1	1	1	5	1
308-0006/64 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	18JUN2013 /35	14NOV2014 /506	I	1	1	1	5	2
	Renal and urinary disorders/ Acute prerenal failure/ PRE-RENAL AZOTEMIA	27JUN2013 /44	14NOV2014 /506	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0006/64 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Wheezing/ WHEEZING	18JUN2013 /35	18JUL2013 /22	I	1	1	1	5	2
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	20JUN2013 /37	04JUL2013 /8	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	18JUN2013 /35	02JUL2013 /6	C	1	3	1	5	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	20JUN2013 /37	02JUL2013 /6	I	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0006/64 /M/A2/Y	Gastrointestinal disorders/ Stomatitis/ MUCOSITIS ORAL	16JUL2013 /63	14NOV2014 /506	I	1	1	1	4	1
	General disorders and administration site conditions/ Oedema peripheral/ LOWER EDEMA	30JUL2013 /77	14NOV2014 /506	I	1	0	1	5	1
	Gastrointestinal disorders/ Upper gastrointestinal haemorrhage/ UPPER GASTROINTESTINAL BLEEDING	20JUN2013 /37	02JUL2013 /6	C	1	3	1	5 [CD]	3
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	18JUN2013 /35	24JUN2013 /-2	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0006/64 /M/A2/Y	Metabolism and nutrition disorders/ Decreased appetite/ WORSENING ANOREXIA	25JUN2013 /42	14NOV2014 /506	I	1	1	1	5	2
	Infections and infestations/ Pneumonia/ PNEUMONIA	18JUN2013 /35	09JUL2013 /13	C	1	1	3 /18JUN2013 /26JUN2013	5[CD]	2
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSYPNEA	09JUN2013 /26	18JUN2013 /-8	I	1	0	1	5	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	09JUN2013 /26	20JUL2013 /24	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0006/64 /M/A2/Y	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	16MAY2013 /2	17JUN2013 /-9	C	1	1	1	5	2
	General disorders and administration site conditions/ Injection site pain/ INJECTION SITE PAIN	21MAY2013 /7	28MAY2013 /-29	C	1	0	1	2	1
308-0008/47 /M/A2/Y	Injury, poisoning and procedural complications/ Wound complication/ WOUND PAIN	04NOV2013 /104	26DEC2013 /163	I	1	1	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	02NOV2013 /102	04NOV2013 /111	C	1	3	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0008/47 /M/A2/Y	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	13OCT2013 /82	26DEC2013 /163	I	1	1	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	11SEP2013 /50	14SEP2013 /60	I	1	1	1	4	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	10OCT2013 /79	25OCT2013 /101	I	1	1	1	5[PD]	1
	Gastrointestinal disorders/ Mouth ulceration/ ORAL ULCER	28SEP2013 /67	26DEC2013 /163	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0008/47 /M/A2/Y	Musculoskeletal and connective tissue disorders/ Flank pain/ FLANK SORENESS	28SEP2013 /67	26DEC2013 /163	C	1	1	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	24SEP2013 /63	28SEP2013 /74	C	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	10SEP2013 /49	26DEC2013 /163	C	1	1	1	5	2
	General disorders and administration site conditions/ Non-cardiac chest pain/ NON-CARDIAC CHEST PAIN	03SEP2013 /42	26DEC2013 /163	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0008/47 /M/A2/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to bone/ BONE METASTASIS FROM HCC	29OCT2013 /98	19NOV2013 /126	C	1	2	1	5 [PD]	3
	Respiratory, thoracic and mediastinal disorders/ Throat irritation/ THROAT ITCHING	13AUG2013 /21	26DEC2013 /163	C	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Back pain/ RIGHT UPPER GUARDANT BACK PAIN	23JUL2013 /0	26DEC2013 /163	C	1	1	1	5	1
308-0009/61 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Wheezing/ WHEEZING	12SEP2013 /55	12SEP2013 /7	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0009/61 /M/A2/N	Vascular disorders/ Hypotension/ HYPOTENSION	12SEP2013 /55	12SEP2013 /7	I	1	1	1	5	3
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	09SEP2013 /52	12SEP2013 /7	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	12SEP2013 /55	12SEP2013 /7	C	1	1	1	5	2
	Renal and urinary disorders/ Acute kidney injury/ ACUTE RENAL FAILURE	05SEP2013 /48	12SEP2013 /7	C	1	0	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0009/61 /M/A2/N	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	07SEP2013 /50	11SEP2013 /6	I	1	1	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	22JUL2013 /3	25JUL2013 /-42	I	1	1	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	22AUG2013 /34	12SEP2013 /7	C	1	2	1	5	1
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	31AUG2013 /43	12SEP2013 /7	I	1	1	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0009/61 /M/A2/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	02SEP2013 /45	12SEP2013 /7	C	1	1	1	4	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	31AUG2013 /43	12SEP2013 /7	C	1	1	1	4	3
	Investigations/ Weight decreased/ WEIGHT LOSS	15AUG2013 /27	12SEP2013 /7	C	1	0	1	4	1
	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	08AUG2013 /20	12SEP2013 /7	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0009/61 /M/A2/N	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASE	25JUL2013 /6	08AUG2013 /-28	C	1	0	1	4	2
	Infections and infestations/ Abdominal infection/ INTRA -ABDOMINAL INFECTION	07SEP2013 /50	12SEP2013 /7	C	4	3	2	5[Intra -Abdominal Infection]	3
	General disorders and administration site conditions/ Pyrexia/ FEVER	05SEP2013 /48	12SEP2013 /7	I	1	1	1	4	1
	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN ITCHING	26AUG2013 /38	12SEP2013 /7	C	1	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
308-0009/61 /M/A2/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	22JUL2013 /3	31AUG2013 /-5	C	1	1	1	5	2
	Infections and infestations/ Orchitis/ CHRONIC ORCHITIS	23JUL2013 /4	08AUG2013 /-28	C	1	1	1	5[Chronic Orchitis]	2
	Gastrointestinal disorders/ Upper gastrointestinal haemorrhage/ UPPER GASTROINTESTINAL BLEEDING	23JUL2013 /4	08AUG2013 /-28	C	1	3	3 /25JUL2013 /01AUG2013	4[CD]	3
309-0006/56 /M/A2/N	Vascular disorders/ Essential hypertension/ ESSENTIAL HYPERTENSION	10DEC2012 /14	24MAY2015 /671	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0006/56 /M/A2/N	Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	04JUN2013 /190	17JUN2013 /-35	I	1	1	1	5	2
	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	23APR2013 /148	06MAY2013 /-77	C	1	1	1	5	1
	Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING OF LOW BACK PAIN	07JAN2013 /42	25FEB2013 /-147	I	1	1	1	5	2
	Skin and subcutaneous tissue disorders/ Alopecia/ ALOPECIA	24DEC2012 /28	25FEB2013 /-147	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0007/58 /M/A2/N	Gastrointestinal disorders/ Ascites/ ASCITES	10MAR2013 /83	12JUN2013 /107	C	1	0	1	5	1
	Nervous system disorders/ Dizziness/ DIZZINESS	21MAR2013 /94	26APR2013 /60	I	1	0	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ LEG EDEMA	18MAR2013 /91	26APR2013 /60	C	1	1	1	5	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	10MAR2013 /83	26APR2013 /60	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0007/58 /M/A2/N	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	11MAR2013 /84	26APR2013 /60	I	1	1	1	5	2
	General disorders and administration site conditions/ Non-cardiac chest pain/ NON-CARDIAC CHEST PAIN	08MAR2013 /81	24MAR2013 /27	I	1	1	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ SKIN ITCH	31DEC2012 /14	12JUN2013 /107	I	1	1	1	5	1
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	29JAN2013 /43	04FEB2013 /-21	C	1	1	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0013/45 /M/A2/N	Injury, poisoning and procedural complications/ Ligament sprain/ NECK SPRAIN	18JUL2013 /28	25JUL2013 /-35	I	1	1	1	5	2
	Cardiac disorders/ Cardiomegaly/ CARDIOMEGALY	05SEP2013 /77	17OCT2013 /49	C	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	05SEP2013 /77	17OCT2013 /49	I	1	0	1	5	1
309-0014/39 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Epistaxis/ EPISTAXIS	06JUL2013 /16	27AUG2013 /-2	I	2	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0014/39 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Epistaxis/ WORSENING OF EPISTAXIS	27AUG2013 /68	17SEP2013 /19	I	1	3	1	5	3
	Respiratory, thoracic and mediastinal disorders/ Nasal congestion/ NASAL STUFFINESS	08AUG2013 /49	18JAN2014 /142	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Rhinorrhoea/ RHINORRHEA	19JUL2013 /29	08AUG2013 /-21	I	1	1	1	5	2
	Injury, poisoning and procedural complications/ Wound necrosis/ WORSENING OF LEFT BIG TOE WOUND NECROSIS	07JUL2013 /17	05AUG2013 /-24	C	1	3	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0019/68 /M/A2/N	Gastrointestinal disorders/ Dry mouth/ DRY MOUTH	08JUL2015 /379	20JUL2015 /0	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Nasal obstruction/ NASAL OBSTRUCTION	06JUL2015 /377	13JUL2015 /-7	I	1	1	1	5	1
	Skin and subcutaneous tissue disorders/ Cold sweat/ COLD SWEATING	16JUN2015 /357	20JUL2015 /0	I	1	0	1	5	1
	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	02JUN2015 /343	Unknown/NA	I	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0019/68 /M/A2/N	Nervous system disorders/ Dizziness/ DIZZINESS	26MAY2015 /336	Unknown/NA	I	6	1	1	5	1
	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	24MAR2015 /273	05MAY2015 /-76	I	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ BLOOD SPUTUM	17APR2015 /297	Unknown/NA	I	6	1	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	26AUG2014 /63	09SEP2014 /-314	C	1	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0019/68 /M/A2/N	Nervous system disorders/ Vascular encephalopathy/ SUBCORTICAL ARTERIOSCLEROTIC ENCEPHALOPATHY	19AUG2014 /56	Unknown/NA	C	6	0	1	5	1
	Nervous system disorders/ Cerebral arteriosclerosis/ INTRACRANIAL ATHEROSCLEROSIS	19AUG2014 /56	Unknown/NA	C	6	0	1	5	1
	General disorders and administration site conditions/ Oedema peripheral/ PITTING EDEMA OF BOTH FOOT	26AUG2014 /63	23SEP2014 /-300	I	1	1	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	26AUG2014 /63	Unknown/NA	I	6	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0019/68 /M/A2/N	General disorders and administration site conditions/ Fatigue/ FATIGUE	06AUG2014 /43	Unknown/NA	C	6	0	1	2	2
	Metabolism and nutrition disorders/ Decreased appetite/ WORSENING OF POOR APPETITE	06AUG2014 /43	26AUG2014 /-328	C	2	1	3 /12AUG2014 /26AUG2014	2	3
	Psychiatric disorders/ Depression/ DEPRESSIVE DISORDER	05AUG2014 /42	Unknown/NA	C	6	1	1	5	1
	Ear and labyrinth disorders/ Tinnitus/ LEFT TINNITUS	05AUG2014 /42	Unknown/NA	I	6	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0019/68 /M/A2/N	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH	22JUL2014 /28	29JUL2014 /-356	C	1	1	1	5	2
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	15JUL2014 /21	12AUG2014 /-342	C	1	0	1	3	1
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	15JUL2014 /21	29JUL2014 /-356	C	1	0	1	3	1
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	15JUL2014 /21	29JUL2014 /-356	C	1	0	1	2	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0019/68 /M/A2/N	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	15JUL2014 /21	29JUL2014 /-356	C	1	0	1	2	3
309-0027/49 /M/A2/Y	Eye disorders/ Ocular icterus/ ICTERIC SCLERA	29DEC2014 /56	12JUN2015 /151	C	1	0	1	5	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	27JAN2015 /85	27JAN2015 /15	I	1	1	1	5	1
	Gastrointestinal disorders/ Ascites/ WORSENING OF ASCITES	22DEC2014 /49	25JAN2015 /13	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0027/49 /M/A2/Y	Gastrointestinal disorders/ Ascites/ WORSENING OF ASCITES	26JAN2015 /84	12JUN2015 /151	C	1	2	1	5 [PD]	3
	Gastrointestinal disorders/ Duodenal ulcer/ DUODENAL ULCERS	24JAN2015 /82	12JUN2015 /151	C	1	1	1	5	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	19JAN2015 /77	16FEB2015 /35	C	1	2	1	5	3
	Musculoskeletal and connective tissue disorders/ Muscle spasms/ MUSCLE CRAMPING	05JAN2015 /63	16FEB2015 /35	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0027/49 /M/A2/Y	Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA	05JAN2015 /63	19JAN2015 /7	C	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Spinal osteoarthritis/ SPONDYLOSIS OF L-SPINE	29DEC2014 /56	12JUN2015 /151	C	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ RIGHT PLEURAL EFFUSION	29DEC2014 /56	26FEB2015 /45	C	1	1	1	5	2
	Investigations/ Hepatic enzyme increased/ LIVER ENZYME INCREASED	22DEC2014 /49	12JUN2015 /151	I	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0029/50 /M/A2/Y	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	17FEB2015 /78	19FEB2015 /10	I	1	0	1	5	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	06MAR2015 /95	09APR2015 /59	C	1	1	1	5	2
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT NEOPLASM PROGRESSION	04MAR2015 /93	09APR2015 /59	C	4	1	1	5[PD]	3
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT NEOPLASM PROGRESSION	26FEB2015 /87	03MAR2015 /22	C	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0029/50 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Productive cough/ PRODUCTIVE COUGH	16FEB2015 /77	09APR2015 /59	I	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ BLOOD SPUTUM	21JAN2015 /51	11MAR2015 /30	I	1	1	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	24FEB2015 /85	24FEB2015 /15	I	1	1	1	5	1
	Nervous system disorders/ Hepatic encephalopathy/ HEPATIC ENCEPHALOPATHY	09FEB2015 /70	26FEB2015 /17	I	1	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0029/50 /M/A2/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT NEOPLASM PROGRESSION	09FEB2015 /70	26FEB2015 /17	C	2	1	2	5 [PD]	4
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	09FEB2015 /70	10FEB2015 /1	I	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	09FEB2015 /70	09APR2015 /59	I	1	1	1	5	2
	Gastrointestinal disorders/ Oral pain/ ORAL SORENESS	26JAN2015 /56	09APR2015 /59	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
309-0029/50 /M/A2/Y	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	16JAN2015 /46	16JAN2015 /-24	C	1	1	1	5	2
	General disorders and administration site conditions/ Malaise/ MALAISE	05JAN2015 /35	09APR2015 /59	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ WORSENING OF POOR APPETITE	29DEC2014 /28	09APR2015 /59	I	1	1	1	4	2
	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	15DEC2014 /14	28DEC2014 /-43	I	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0004/50 /F/A2/N	General disorders and administration site conditions/ Pain/ GENERAL SORENESS	05MAR2013 /27	24JUL2013 /98	I	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	05MAR2013 /27	24JUL2013 /98	I	1	0	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ WORSENING ANEMIA	17APR2013 /70	24APR2013 /7	C	1	3	1	5	2
	General disorders and administration site conditions/ Pyrexia/ INTERMITTENT FEVER	11MAY2013 /94	30MAY2013 /43	I	1	1	1	5[Infection ]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0004/50 /F/A2/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	24APR2013 /77	23MAY2013 /36	I	1	1	1	5	2
	Blood and lymphatic system disorders/ Anaemia/ WORSENING ANEMIA	20MAR2013 /42	27MAR2013 /-21	I	1	3	1	5	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	25MAR2013 /47	27MAR2013 /-21	I	1	0	1	5	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	05MAR2013 /27	24JUL2013 /98	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0004/50 /F/A2/N	Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	05MAR2013 /27	11MAR2013 /-37	C	1	3	1	5[Infection ]	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	14FEB2013 /8	15FEB2013 /-61	I	1	0	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	07FEB2013 /1	24JUL2013 /98	C	1	0	1	3	1
310-0005/59 /M/A2/Y	General disorders and administration site conditions/ Chest discomfort/ CHEST DISCOMFORT	22MAY2013 /56	07DEC2013 /187	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0005/59 /M/A2/Y	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ WORSENING SHOULDER SORENESS	28JUN2013 /93	01JUL2013 /28	C	1	1	1	5	2
	Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIA	29MAY2013 /63	11JUN2013 /8	C	1	0	1	5	2
	General disorders and administration site conditions/ Chest discomfort/ CHEST TIGHTNESS	03JUL2013 /98	03SEP2013 /92	I	1	1	1	5	2
	General disorders and administration site conditions/ Malaise/ MALAISE	03APR2013 /7	07DEC2013 /187	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0005/59 /M/A2/Y	Gastrointestinal disorders/ Dysphagia/ DYSPHAGIA	27JUN2013 /92	07AUG2013 /65	I	1	0	1	5	2
	Gastrointestinal disorders/ Vomiting/ VOMITING	28JUN2013 /93	28JUN2013 /25	I	1	1	1	5	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	28JUN2013 /93	28JUN2013 /25	I	1	1	1	5	2
	Nervous system disorders/ Dizziness/ DIZZINESS	28JUN2013 /93	01JUL2013 /28	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0005/59 /M/A2/Y	Metabolism and nutrition disorders/ Decreased appetite/ POOR APPETITE	26JUN2013 /91	07DEC2013 /187	C	1	1	1	5	2
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ HEMOPTYSIS	19JUN2013 /84	03SEP2013 /92	I	1	1	1	5	2
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	29MAY2013 /63	03SEP2013 /92	I	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea paroxysmal nocturnal/ PAROXYMAL NOCTURNAL DYSPNEA	18APR2013 /22	24APR2013 /-40	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0005/59 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Nasal discomfort/ NASAL SORENESS	18APR2013 /22	24APR2013 /-40	I	1	3	1	5	2
	General disorders and administration site conditions/ Chest discomfort/ CHEST DISCOMFORT	01APR2013 /5	21MAY2013 /-13	I	1	0	1	5	1
310-0006/50 /F/A2/Y	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	30DEC2013 /243	05OCT2014 /286	I	1	1	1	5	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	16DEC2013 /229	05OCT2014 /286	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0006/50 /F/A2/Y	Nervous system disorders/ Headache/ HEADACHE	16DEC2013 /229	05OCT2014 /286	I	1	0	1	5	1
	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPRITORY INFECTION	16DEC2013 /229	30DEC2013 /7	C	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Muscle spasms/ LOWER LIMBS CRAMP	28AUG2013 /119	03SEP2013 /-111	I	1	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Back pain/ LOW BACK SORENESS	16OCT2013 /168	05OCT2014 /286	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0006/50 /F/A2/Y	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIGHT SHOULDER DISCOMFORT	10JUL2013 /70	05OCT2014 /286	I	1	1	1	5	2
	General disorders and administration site conditions/ Influenza like illness/ FLU LIKE SYMPTOMS	19JUN2013 /49	02JUL2013 /-174	C	1	1	1	5	2
	Skin and subcutaneous tissue disorders/ Pruritus/ SOLE ITCHING	15MAY2013 /14	19JUN2013 /-187	I	1	0	1	5	1
310-0007/74 /M/A2/N	Gastrointestinal disorders/ Peptic ulcer/ PEPTIC ULCER	25FEB2014 /257	10JUN2014 /40	C	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0007/74 /M/A2/N	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	22MAY2014 /343	26MAY2014 /25	C	1	1	1	5	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	21APR2014 /312	Unknown/NA	C	6	0	1	5	2
	Gastrointestinal disorders/ Dry mouth/ DRY MOUTH	01FEB2014 /233	Unknown/NA	C	6	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Epistaxis/ EPISTAXIS	23FEB2014 /255	28FEB2014 /-62	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0007/74 /M/A2/N	Ear and labyrinth disorders/ Ear discomfort/ EAR DISCOMFORT	07FEB2014 /239	Unknown/NA	C	6	0	1	5	1
	Skin and subcutaneous tissue disorders/ Skin exfoliation/ FEET DESQUAMATION	05SEP2013 /84	Unknown/NA	C	6	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Oropharyngeal pain/ SORETHROAT	16JAN2014 /217	23JAN2014 /-98	C	1	1	1	5	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	15AUG2013 /63	20APR2014 /-11	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0007/74 /M/A2/N	Investigations/ Low density lipoprotein increased/ LOW-DENSITY LIPOPROTEIN CHOLESTEROL INCREASE	16AUG2013 /64	06MAY2014 /5	C	1	1	1	5	2
	General disorders and administration site conditions/ Chest discomfort/ MILD CHEST TIGHTNESS	07NOV2013 /147	Unknown/NA	I	6	0	1	5	1
	Renal and urinary disorders/ Dysuria/ DYSURIA	31OCT2013 /140	Unknown/NA	I	6	0	1	5	1
	Nervous system disorders/ Hypoaesthesia/ PALM NUMBNESS	24OCT2013 /133	Unknown/NA	I	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0007/74 /M/A2/N	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ RIGHT CHEST WALL DULL DISCOMFORT	30AUG2013 /78	Unknown/NA	I	6	0	1	5	1
310-0009/46 /M/A2/N	Gastrointestinal disorders/ Abdominal pain/ WORSENING ABDOMINAL PAIN	25SEP2013 /49	30OCT2013 /35	I	1	3	1	5 [PD]	3
310-0010/34 /F/A2/N	Gastrointestinal disorders/ Pancreatitis/ PANCREATITIS	09OCT2013 /44	23OCT2013 /37	I	1	1	1	5	3
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	01OCT2013 /36	11DEC2013 /86	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0010/34 /F/A2/N	General disorders and administration site conditions/ Pyrexia/ FEVER	01OCT2013 /36	01OCT2013 /15	I	1	1	1	5	3
	Gastrointestinal disorders/ Gastric ulcer/ GASTRIC ULCER	25SEP2013 /30	11DEC2013 /86	I	1	1	1	5	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	23SEP2013 /28	23OCT2013 /37	I	1	0	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	23SEP2013 /28	23OCT2013 /37	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0010/34 /F/A2/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	23SEP2013 /28	23OCT2013 /37	I	1	1	3 /23SEP2013 /Unknown	5	2
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ MALIGNANT NEOPLASM PROGRESSION	23SEP2013 /28	23OCT2013 /37	C	1	3	2	5[PD]	3
310-0011/52 /M/A2/N	Nervous system disorders/ Hypoaesthesia/ RIGHT INGUINAL AREA NUMBNESS	17NOV2013 /24	09JAN2014 /7	C	1	0	1	5	1
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	08NOV2013 /15	23JAN2014 /21	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
310-0014/64 /M/A2/N	Musculoskeletal and connective tissue disorders/ Arthralgia/ BOTH HIP PAIN	27DEC2014 /94	16JUN2015 /202	C	1	1	1	5	1
	Injury, poisoning and procedural complications/ Wound/ RIGHT LOWER ABDOMINAL WOUND FROM IA PORT REMOVAL	16DEC2014 /83	24DEC2014 /28	C	1	0	1	5	1
	General disorders and administration site conditions/ Catheter site pain/ PORT-A PAIN	21NOV2014 /58	15DEC2014 /19	C	1	2	1	5	1
311-0004/68 /M/A2/Y	Nervous system disorders/ Cerebral haemorrhage/ INTRACEREBRAL HEMORRHAGE	14OCT2013 /14	16NOV2013 /33	C	1	3	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
311-0004/68 /M/A2/Y	General disorders and administration site conditions/ Disease progression/ WORSENING OF HEPATIC CARCINOMA	14OCT2013 /14	16NOV2013 /33	C	4	2	1	4 [PD]	3
	Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ RIGHT INTERCOSTAL PAIN	02OCT2013 /2	16NOV2013 /33	I	1	1	1	5	2
311-0005/58 /M/A2/N	General disorders and administration site conditions/ Non-cardiac chest pain/ MUSULOSKELETAL CHEST PAIN	18NOV2013 /28	24NOV2013 /-29	I	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Back pain/ LEFT BACK PAIN	23DEC2013 /63	03AUG2014 /223	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
311-0005/58 /M/A2/N	Musculoskeletal and connective tissue disorders/ Back pain/ RIGHT BACK PAIN	25NOV2013 /35	03AUG2014 /223	I	1	1	1	5	2
311-0006/73 /F/A2/Y	General disorders and administration site conditions/ Disease progression/ WORSENING OF HEPATIC CARCINOMA	16JAN2014 /70	16MAR2014 /66	C	4	2	1	5 [PD]	3
	Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	16DEC2013 /39	16MAR2014 /66	I	1	1	1	5	2
	Gastrointestinal disorders/ Mouth ulceration/ ORAL ULCER	17NOV2013 /10	16MAR2014 /66	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
311-0009/51 /F/A2/N	Investigations/ Weight decreased/ BODY WEIGHT LOSS	26AUG2014 /42	02SEP2014 /-28	C	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	05AUG2014 /21	23SEP2014 /-7	I	1	1	1	5	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL FULLNESS	29JUL2014 /14	19AUG2014 /-42	I	1	1	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ COUGH (WITH BLOODY CONTENT)	29JUL2014 /14	26AUG2014 /-35	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
311-0009/51 /F/A2/N	Musculoskeletal and connective tissue disorders/ Musculoskeletal pain/ RIGHT BUTTOCK PAIN	22JUL2014 /7	Unknown/NA	I	6	1	1	5	2
311-0010/47 /M/A2/Y	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	07OCT2014 /35	21OCT2014 /-247	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	30SEP2014 /28	07OCT2014 /-261	I	1	1	1	5	2
311-0011/46 /M/A2/N	Musculoskeletal and connective tissue disorders/ Arthralgia/ BILATERAL KNEE PAIN	24DEC2014 /55	Unknown/NA	I	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
311-0012/55 /M/A2/Y	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS	28MAY2015 /119	04JUN2015 /-21	C	1	1	1	5	1
401-0001/70 /M/A7/N	Gastrointestinal disorders/ Portalhypertensivegastropathy/ CONGESTIVE GASTROPATHY	14JUN2013 /9	Unknown/NA	I	6	1	1	5	2
	General disorders and administration site conditions/ Pain/ PAIN	27JUN2013 /22	Unknown/NA	I	6	3	1	5	2
	General disorders and administration site conditions/ Injection site reaction/ INJECTION SITE REACTION	05JUN2013 /0	06JUN2013 /1	I	1	0	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
401-0002/56 /M/A7/N	Gastrointestinal disorders/ Constipation/ CONSTIPATION	24JUL2013 /35	30JUL2013 /27	C	1	1	1	5	1
	Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA	25JUL2013 /36	28JUL2013 /25	I	1	1	1	5	2
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to spine/ SPINE METASTASIS	22JUL2013 /33	05AUG2013 /33	C	1	3	1	5 [PD]	3
	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	19JUN2013 /0	25JUL2013 /22	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0001/35 /M/A7/Y	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	10JUN2013 /49	Unknown/NA	C	6	0	3 /10JUN2013 /Unknown	4	3
	Psychiatric disorders/ Insomnia/ INSOMNIA	02JUN2013 /41	Unknown/NA	C	6	0	1	4	1
	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH	28MAY2013 /36	Unknown/NA	C	6	0	1	4	1
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	03JUN2013 /42	09JUN2013 /20	C	1	0	2	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0001/35 /M/A7/Y	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	27MAY2013 /35	02JUN2013 /13	C	1	0	3 /27MAY2013 /03JUN2013	4	3
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	08MAY2013 /16	Unknown/NA	C	6	1	1	4	1
	General disorders and administration site conditions/ Injection site pain/ PAIN(INJECTION SITE)	29APR2013 /7	03JUN2013 /14	C	1	0	1	1	1
	Skin and subcutaneous tissue disorders/ Pruritus generalised/ ITCHING (WHOLE BODY)	22APR2013 /0	Unknown/NA	I	6	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0001/35 /M/A7/Y	General disorders and administration site conditions/ Fatigue/ FATIGUE	22APR2013 /0	Unknown/NA	C	6	0	1	2	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	22APR2013 /0	22APR2013 /-28	I	1	0	1	2	1
402-0002/58 /M/A7/N	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	10JUL2013 /78	Unknown/NA	C	6	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	03JUL2013 /71	Unknown/NA	C	6	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0002/58 /M/A7/N	Injury, poisoning and procedural complications/ Compression fracture/ PATHOLOGIC COMPRESSION FRACTURE IN T11	23MAY2013 /30	04JUN2013 /-35	C	1	3	3 /21MAY2013 /11JUN2013	5[CD]	3
	General disorders and administration site conditions/ Fatigue/ FATIGUE	30APR2013 /7	Unknown/NA	C	6	0	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	30APR2013 /7	07MAY2013 /-63	I	1	0	1	3	1
	General disorders and administration site conditions/ Oedema peripheral/ BOTH LEG EDEMA	01MAY2013 /8	Unknown/NA	C	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0002/58 /M/A7/N	Musculoskeletal and connective tissue disorders/ Flank pain/ BOTH, FLANK PAIN	23APR2013* /0	06JUN2013 /-33	C	1	1	1	5	2
402-0005/70 /M/A7/N	Psychiatric disorders/ Insomnia/ INSOMNIA	15AUG2013 /98	Unknown/NA	C	6	1	1	5	1
	General disorders and administration site conditions/ Chest discomfort/ CHEST DISCOMFORT(NON CARDIAC)	15AUG2013 /98	Unknown/NA	C	6	0	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING(BOTH THIGH)	11JUL2013 /63	Unknown/NA	C	6	1	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0005/70 /M/A7/N	Skin and subcutaneous tissue disorders/ Pruritus generalised/ ITCHING(WHOLE BODY)	15JUN2013 /37	10JUL2013 /-13	C	1	1	1	2	1
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING(BOTH THIGH)	09MAY2013 /0	14JUN2013 /-39	C	1	0	1	3	1
	Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIA	13JUN2013 /35	19JUN2013 /-34	C	1	1	3 /13JUN2013 /20JUN2013	3	3
402-0010/50 /M/A7/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ PROGRESSION OF NEOPLASTIC DISEASE	13JUL2013 /54	13JUL2013 /26	C	4	0	1	5[PD]	5

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0010/50 /M/A7/Y	Investigations/ International normalised ratio increased/ INR INCREASED	24JUN2013 /35	07JUL2013 /20	C	1	0	3 /Unknown/U nknown	5	3
	Respiratory, thoracic and mediastinal disorders/ Productive cough/ SPUTUM	04JUN2013 /15	Unknown/NA	C	6	1	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING(UPPER BODY)	28MAY2013 /8	10JUN2013 /-7	C	1	0	1	2	1
402-0022/60 /F/A7/Y	Musculoskeletal and connective tissue disorders/ Pain in extremity/ RIGHT THIGH PAIN	18OCT2013 /60	Unknown/NA	C	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0022/60 /F/A7/Y	Musculoskeletal and connective tissue disorders/ Pain in extremity/ THIGH PAIN	21OCT2013 /63	Unknown/NA	C	6	1	1	5 [CD]	3
	Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT HIP PAIN	21OCT2013 /63	Unknown/NA	C	6	1	1	5 [CD]	3
	Musculoskeletal and connective tissue disorders/ Arthralgia/ RIGHT PAIN (KNEE)	25SEP2013 /37	02OCT2013 /-40	C	1	1	1	5	2
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	27SEP2013 /39	09OCT2013 /-33	C	1	2	1	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0022/60 /F/A7/Y	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	05SEP2013 /17	11SEP2013 /-61	C	1	2	1	3	3
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	30AUG2013 /11	04SEP2013 /-68	C	1	0	1	3	2
402-0023/57 /M/A7/Y	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	19NOV2013 /78	Unknown/NA	C	6	2	1	2	2
	Investigations/ Aspartate aminotransferase increased/ INCREASED AST	19NOV2013 /78	Unknown/NA	C	6	1	1	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0023/57 /M/A7/Y	Nervous system disorders/ Dizziness/ DIZINESS	05NOV2013 /64	Unknown/NA	C	6	0	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	06NOV2013 /65	Unknown/NA	C	6	1	1	4	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	12NOV2013 /71	18NOV2013 /-1	C	1	2	1	2	3
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	08OCT2013 /36	11NOV2013 /-8	C	1	2	1	2	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0023/57 /M/A7/Y	Gastrointestinal disorders/ Gingival pain/ GINGIVAL PAIN	05OCT2013 /33	14OCT2013 /-36	C	1	0	1	3	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	01OCT2013 /29	07OCT2013 /-43	C	1	2	1	2	3
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	10SEP2013 /8	30SEP2013 /-50	C	1	2	1	2	2
402-0029/49 /M/A7/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ PROGRESSION OF NEOPLASTIC DISEASE	04JAN2014 /54	04JAN2014 /5	C	4	3	1	5 [PD]	5

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0029/49 /M/A7/Y	Eye disorders/ Cataract/ CATARACT	03DEC2013 /22	Unknown/NA	C	6	1	1	3	1
	Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNEA	01DEC2013 /20	Unknown/NA	C	6	0	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	20NOV2013 /9	Unknown/NA	C	6	1	1	2	1
402-0032/49 /F/A7/Y	Nervous system disorders/ Headache/ HEADACHE	19MAR2014 /103	Unknown/NA	C	6	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0032/49 /F/A7/Y	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	06MAR2014 /90	17MAR2014 /25	C	1	3	1	5 [PD]	2
	General disorders and administration site conditions/ Pain/ WHOLE BODY PAIN	13FEB2014 /69	17FEB2014 /-3	C	1	0	1	4	2
	General disorders and administration site conditions/ Oedema peripheral/ EDEMA OF BOTH HANDS	03FEB2014 /59	19FEB2014 /-1	C	1	0	1	3	1
	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	09DEC2013 /3	Unknown/NA	C	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
402-0034/43 /F/A7/Y	General disorders and administration site conditions/ Face oedema/ FACIAL EDEMA	25MAR2014 /96	Unknown/NA	C	6	0	1	4	1
	Nervous system disorders/ Peripheral sensory neuropathy/ SENSORY NEUROPATHY (LEFT EXTREMITIES)	18FEB2014 /61	Unknown/NA	C	6	0	1	3	1
	Infections and infestations/ Urinary tract infection/ URINARY INFECTION	12FEB2014 /55	19FEB2014 /-99	C	1	1	3 /13FEB2014 /19FEB2014	5	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	19DEC2013 /0	Unknown/NA	C	6	0	1	2	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0004/37 /M/A7/Y	Gastrointestinal disorders/ Stomatitis/ MUCOSITIS ORAL	10OCT2013 /90	Unknown/NA	I	6	1	1	5	2
	Blood and lymphatic system disorders/ Febrile neutropenia/ FEBRILE NEUTROPENIA	15OCT2013 /95	21OCT2013 /26	C	1	1	1	5[Other Systemic Chemotherap y]	3
	General disorders and administration site conditions/ Pyrexia/ FEVER	13OCT2013 /93	17OCT2013 /22	C	1	1	1	5	1
	General disorders and administration site conditions/ Chills/ CHILLS	13OCT2013 /93	17OCT2013 /22	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0004/37 /M/A7/Y	Nervous system disorders/ Dizziness/ DIZZINESS	23SEP2013 /73	23SEP2013 /-2	C	1	0	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	23SEP2013 /73	23SEP2013 /-2	C	1	0	1	5	1
	Skin and subcutaneous tissue disorders/ Pruritus/ PRURITUS (SCALP)	01SEP2013* /51	30SEP2013 /5	C	1	0	1	3	1
	Reproductive system and breast disorders/ Nipple pain/ PAIN (RIGHT NIPPLE)	17JUL2013 /5	31JAN2014* /128	C	1	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0004/37 /M/A7/Y	Gastrointestinal disorders/ Dyspepsia/ HEARTBURN	24AUG2013 /43	Unknown/NA	C	6	1	1	2	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	01AUG2013* /20	Unknown/NA	I	6	0	1	2	1
	Skin and subcutaneous tissue disorders/ Alopecia/ ALOPECIA	12JUL2013* /0	31AUG2013* /-25	C	1	0	1	4	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMEN PAIN	24AUG2013 /43	26AUG2013 /-30	I	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
403-0004/37 /M/A7/Y	Nervous system disorders/ Headache/ HEADACHE	24AUG2013 /43	24AUG2013 /-32	I	1	0	1	5	1
	Musculoskeletal and connective tissue disorders/ Arthralgia/ ARTHRALGIA	12JUL2013* /0	31JUL2013* /-56	C	1	0	1	3	1
	Gastrointestinal disorders/ Abdominal pain/ PAIN (ABDOMEN)	24JUL2013 /12	31JUL2013* /-56	I	1	0	1	5	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	03OCT2013 /83	21OCT2013 /26	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
404-0003/53 /M/A7/Y	General disorders and administration site conditions/ Disease progression/ PROGRESSIVE DISEASE OF HCC	30SEP2013 /20	20OCT2013 /26	I	4	1	2	4 [PD]	5
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	03OCT2013 /23	Unknown/NA	C	6	0	1	5	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	17SEP2013 /7	Unknown/NA	C	6	0	1	5	3
	Investigations/ Blood alkaline phosphatase increased/ ELEVATED ALP	01OCT2013 /21	Unknown/NA	C	6	0	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
404-0003/53 /M/A7/Y	Investigations/ Blood alkaline phosphatase increased/ ELEVATED ALP	17SEP2013 /7	30SEP2013 /6	C	3	0	1	5	1
	Investigations/ International normalised ratio increased/ INR INCREASED	16SEP2013 /6	Unknown/NA	C	6	0	1	5	1
404-0004/62 /F/A7/Y	Musculoskeletal and connective tissue disorders/ Neck pain/ NECK PAIN	22DEC2013 /68	Unknown/NA	C	6	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Muscular weakness/ BOTH LEG WEAKNESS	28NOV2013 /44	Unknown/NA	C	6	1	1	5	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
404-0004/62 /F/A7/Y	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	26NOV2013 /42	Unknown/NA	C	6	1	1	5	2
	Musculoskeletal and connective tissue disorders/ Pain in extremity/ BOTH ARM PAIN	28NOV2013 /44	Unknown/NA	C	6	1	1	5 [PD]	3
	Gastrointestinal disorders/ Vomiting/ VOMITING FROM OVEREATING	15OCT2013 /0	15OCT2013 /-48	I	1	0	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	08NOV2013 /24	09NOV2013 /-23	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
404-0004/62 /F/A7/Y	Gastrointestinal disorders/ Vomiting/ VOMITING	01NOV2013 /17	02NOV2013 /-30	I	1	0	1	3	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	26OCT2013 /11	26OCT2013 /-37	I	1	0	1	5	1
	Respiratory, thoracic and mediastinal disorders/ Respiratory failure/ RESPIRATORY FAILURE	24DEC2013 /70	Unknown/NA	C	6	3	1	5	4
	General disorders and administration site conditions/ Mucosal inflammation/ MUCOSITIS	21DEC2013 /67	Unknown/NA	C	6	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
404-0004/62 /F/A7/Y	Infections and infestations/ Urosepsis/ UROSEPSIS	25DEC2013 /71	Unknown/NA	C	6	1	1	5	4
	Infections and infestations/ Sepsis/ SEPSIS	24DEC2013 /70	Unknown/NA	C	6	1	1	5	4
	Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	24DEC2013 /70	Unknown/NA	C	6	2	1	5	2
	Metabolism and nutrition disorders/ Metabolic acidosis/ METABOLIC ACIDOSIS	24DEC2013 /70	Unknown/NA	C	6	3	1	5	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
404-0004/62 /F/A7/Y	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	23DEC2013 /69	Unknown/NA	C	6	0	1	5	3
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	23DEC2013 /69	24DEC2013 /22	C	3	0	1	5 [PD]	3
	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	16DEC2013 /62	Unknown/NA	C	6	0	1	5	1
	Vascular disorders/ Hypotension/ HYPOTENSION	24DEC2013 /70	Unknown/NA	C	6	1	1	5	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
404-0004/62 /F/A7/Y	Nervous system disorders/ Somnolence/ SOMNOLENCE	24DEC2013 /70	Unknown/NA	C	6	2	1	5	4
	General disorders and administration site conditions/ Asthenia/ GENERAL WEAKNESS	18DEC2013 /64	Unknown/NA	C	6	0	1	5	2
	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	17DEC2013 /63	Unknown/NA	C	6	0	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	15DEC2013 /61	16DEC2013 /14	I	1	1	1	5	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
404-0004/62 /F/A7/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	14DEC2013 /60	21DEC2013 /19	I	1	1	1	5	2
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	15DEC2013 /61	15DEC2013 /13	I	1	1	1	5	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	14DEC2013 /60	14DEC2013 /12	I	3	1	1	5	3
	General disorders and administration site conditions/ Disease progression/ PROGRESSION OF HCC	10DEC2013 /56	25DEC2013 /23	C	4	1	1	5 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
404-0004/62 /F/A7/Y	Gastrointestinal disorders/ Constipation/ CONSTIPATION	12DEC2013 /58	14DEC2013 /12	C	1	1	1	5	2
	Investigations/ Blood creatinine increased/ CREATININE INCREASED	02DEC2013 /48	Unknown/NA	C	6	0	1	5	1
	Investigations/ Blood alkaline phosphatase increased/ ELEVATED ALP	02DEC2013 /48	22DEC2013 /20	C	1	0	1	5	1
	Gastrointestinal disorders/ Vomiting/ VOMITING	24NOV2013 /40	25NOV2013 /-7	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
404-0004/62 /F/A7/Y	Gastrointestinal disorders/ Nausea/ NAUSEA	14NOV2013 /30	14NOV2013 /-18	I	1	0	1	4	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	08NOV2013 /24	09NOV2013 /-23	I	1	0	1	3	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	01NOV2013 /17	02NOV2013 /-30	I	1	0	1	3	1
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	04NOV2013 /20	17NOV2013 /-15	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
404-0004/62 /F/A7/Y	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	26OCT2013 /11	03NOV2013 /-29	C	1	0	1	2	1
	Gastrointestinal disorders/ Nausea/ NAUSEA	26OCT2013 /11	26OCT2013 /-37	C	1	0	1	5	1
	Gastrointestinal disorders/ Nausea/ NAUSEA FROM OVEREATING	15OCT2013 /0	15OCT2013 /-48	I	1	0	1	5	1
405-0001/55 /M/A7/Y	Nervous system disorders/ Dysgeusia/ DYSGUESIA	14JUN2013 /53	30JUL2013 /27	I	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0001/55 /M/A7/Y	Skin and subcutaneous tissue disorders/ Alopecia/ ALOPECIA	14JUN2013 /53	30JUL2013 /27	I	1	0	1	3	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	01MAY2013 /9	30JUL2013 /27	I	1	0	1	3	1
405-0005/35 /M/A6/N	Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	13OCT2013 /172	20OCT2013 /-64	C	1	1	1	4	2
405-0012/72 /M/A7/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to central nervous system/ BRAIN METASTASES	06NOV2013 /175	02DEC2013 /42	C	4	3	1	5 [PD]	5

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0012/72 /M/A7/Y	Injury, poisoning and procedural complications/ Subdural haematoma/ CHRONIC SUBDURAL HEMATOMA	06NOV2013 /175	02DEC2013 /42	C	4	3	1	5 [PD]	5
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING	17OCT2013 /155	Unknown/NA	I	6	1	1	3	1
	Skin and subcutaneous tissue disorders/ Pruritus/ ITCHING	12OCT2013 /150	16OCT2013 /-5	I	1	1	1	3	3
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to central nervous system/ BRAIN METASTASIS	06NOV2013 /175	Unknown/NA	C	6	3	1	5 [Cerebral Hemorrhage]	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0012/72 /M/A7/Y	Nervous system disorders/ Cerebral haemorrhage/ CEREBRAL HEMORRHAGE	21OCT2013 /159	25OCT2013 /4	C	1	0	1	4 [CD]	3
	Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA	17OCT2013 /155	Unknown/NA	I	6	1	1	3	1
	Eye disorders/ Conjunctival haemorrhage/ SUBCONJUNCTIVAL HEMORRHAGE	12OCT2013 /150	Unknown/NA	I	6	1	1	4	2
	Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA	12OCT2013 /150	16OCT2013 /-5	I	1	1	1	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0012/72 /M/A7/Y	Gastrointestinal disorders/ Dyspepsia/ DYSPEPSIA	10OCT2013 /148	Unknown/NA	I	6	1	1	4	1
	Metabolism and nutrition disorders/ Hypocalcaemia/ HYPOCALCEMIA	07OCT2013 /145	13OCT2013 /-8	C	1	1	1	4	1
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	07OCT2013 /145	13OCT2013 /-8	C	1	0	3 /07OCT2013 /14OCT2013	4	3
	Reproductive system and breast disorders/ Benign prostatic hyperplasia/ BENIGN PROSTATE HYPERTROPHY	02OCT2013 /140	Unknown/NA	I	6	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0012/72 /M/A7/Y	Nervous system disorders/ Paraesthesia/ MILD PARESTHESIA (HERPES ZOSTER SEQUELAE)	23SEP2013 /131	30SEP2013 /-21	I	1	1	1	4	1
	Infections and infestations/ Herpes zoster/ HERPES ZOSTER ON CHEST	07AUG2013 /84	22SEP2013 /-29	C	1	1	1	4	2
405-0019/62 /M/A7/Y	General disorders and administration site conditions/ Disease progression/ PROGRESSION OF HCC DISEASE	05AUG2013 /40	11AUG2013 /18	C	4	0	2	5 [PD]	5
	General disorders and administration site conditions/ Fatigue/ FATIGUE	19JUL2013 /23	Unknown/NA	C	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0019/62 /M/A7/Y	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	18JUL2013 /22	Unknown/NA	I	6	0	1	4	2
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	15JUL2013 /19	17JUL2013 /-7	I	1	0	1	4	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	10JUL2013 /14	Unknown/NA	I	6	1	1	4	2
	Gastrointestinal disorders/ Nausea/ NAUSEA	03JUL2013 /7	Unknown/NA	I	6	1	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0019/62 /M/A7/Y	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	03JUL2013 /7	14JUL2013 /-10	C	1	1	1	4	2
405-0024/69 /M/A7/Y	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ PROGRESSION OF NEOPLASTIC DISEASE-LIVER	12JUL2013 /9	05AUG2013 /33	C	4	1	2	4 [PD]	5
405-0026/67 /M/A7/N	Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH ON BOTH FEET AND BOTH INGUINAL AREA	10JUL2013 /2	19JUL2013 /-68	C	1	0	1	4	1
405-0036/70 /M/A7/N	Metabolism and nutrition disorders/ Hypophosphataemia/ HYPOPHOSPHATEMIA	16DEC2013 /119	Unknown/NA	C	6	1	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0036/70 /M/A7/N	Musculoskeletal and connective tissue disorders/ Musculoskeletal discomfort/ BOTH SHOULDER DISCOMFORT	15NOV2013 /88	Unknown/NA	I	6	1	1	4	1
	Gastrointestinal disorders/ Haematemesis/ HEMATEMESIS	13DEC2013 /116	13DEC2013 /32	I	1	2	1	4	3
	Investigations/ Blood bilirubin increased/ BLOOD BILIRUBIN INCREASED	13DEC2013 /116	Unknown/NA	C	6	0	1	4	3
	Gastrointestinal disorders/ Nausea/ NAUSEA	16OCT2013 /58	Unknown/NA	I	6	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
405-0036/70 /M/A7/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	06SEP2013 /18	Unknown/NA	I	6	0	1	4	1
	General disorders and administration site conditions/ Fatigue/ FATIGUE	01SEP2013 /13	Unknown/NA	I	6	0	1	3	1
	Gastrointestinal disorders/ Dyspepsia/ DYSPEPSIA	25AUG2013 /6	Unknown/NA	I	6	1	1	3	1
501-0004/26 /M/A1/Y	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	25DEC2013 /7	22JAN2014 /-42	C	2	1	1	5[CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0004/26 /M/A1/Y	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOPENIA	22JAN2014 /35	07FEB2014 /-26	C	2	1	1	5 [CD]	2
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROPENIA	07FEB2014 /51	19FEB2014 /-14	C	1	0	1	5 [CD]	1
	Investigations/ Alanine aminotransferase increased/ ALT INCREASE	19FEB2014 /63	05MAR2014 /0	C	1	0	1	5 [Hcc]	1
	Blood and lymphatic system disorders/ Leukopenia/ LEUCOPENIA	07FEB2014 /51	31JUL2014 /148	C	1	0	1	5 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0004/26 /M/A1/Y	Blood and lymphatic system disorders/ Leukopenia/ LEUCOPENIA	25DEC2013 /7	22JAN2014 /-42	C	1	0	1	5[CD]	1
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOPENIA	19FEB2014 /63	31JUL2014 /148	C	1	1	1	5[CD]	2
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOPENIA	07FEB2014 /51	19FEB2014 /-14	C	2	1	1	5[CD]	3
501-0011/61 /M/A1/Y	Investigations/ Haemoglobin decreased/ HEMOGLOBIN DECREASED	26NOV2014 /62	03DEC2014 /-8	C	2	0	3 /26NOV2014 /04DEC2014	5[It Is Related To Liver Cancer.]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0011/61 /M/A1/Y	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	10DEC2014 /76	16DEC2014 /5	C	1	1	1	5 [Diarrhea]	3
	Investigations/ Bilirubin conjugated increased/ DIRECT BILIRUBIN INCREASED	24DEC2014 /90	07JAN2015 /27	C	1	1	1	4 [Hcc]	3
	Investigations/ Bilirubin conjugated increased/ DIRECT BILIRBIN ICREASED	20DEC2014 /86	24DEC2014 /13	C	2	1	1	4 [Hcc]	2
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	12NOV2014 /48	26NOV2014 /-15	C	1	0	1	5 [Hcc]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0011/61 /M/A1/Y	Investigations/ Haemoglobin decreased/ HEMOGLOBN DECREASED	15OCT2014 /20	26NOV2014 /-15	C	2	0	1	5[Splenomeg aly]	2
	Investigations/ Haemoglobin decreased/ HEMOGLOBIN DCREASED	29SEP2014 /4	15OCT2014 /-57	C	2	0	1	5[Splenomeg aly]	1
	Gastrointestinal disorders/ Upper gastrointestinal haemorrhage/ UPPER GASTROINTESTINAL HEMORRHAGE	29DEC2014 /95	07JAN2015 /27	I	2	1	1	5[Hcc]	4
	Gastrointestinal disorders/ Upper gastrointestinal haemorrhage/ UPPER GASTROINTESTINAL HEMORRHAGE	07JAN2015 /104	07JAN2015 /27	I	4	0	1	5[Hcc]	5

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0011/61 /M/A1/Y	Investigations/ Bilirubin conjugated increased/ BLOOD DIRECT BILIRUBIN INCREASED	26NOV2014 /62	20DEC2014 /9	C	2	1	1	4[Hcc]	1
	Gastrointestinal disorders/ Diarrhoea/ DIARRHEA	08DEC2014 /74	08DEC2014 /-3	I	1	0	1	5[Diet]	1
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	29SEP2014 /4	15OCT2014 /-57	C	1	0	1	4	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	26NOV2014 /62	10DEC2014 /-1	C	1	0	1	5[Hcc]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0011/61 /M/A1/Y	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	26NOV2014 /62	03DEC2014 /-8	C	1	0	1	5[Splenomeg aly]	1
	Metabolism and nutrition disorders/ Hypoalbuminaemia/ HYPOALBUMINEMIA	20DEC2014 /86	24DEC2014 /13	C	1	1	1	5[Hcc]	1
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE AMINOTRANSFERASE INCREASED	16DEC2014 /82	07JAN2015 /27	C	1	1	1	4[Hcc]	1
	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	16DEC2014 /82	30DEC2014 /19	C	1	0	1	5[Splenomeg aly]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0011/61 /M/A1/Y	Musculoskeletal and connective tissue disorders/ Back pain/ PAIN IN THE BACK	30DEC2014 /96	30DEC2014 /19	C	1	1	1	5[Hcc]	1
	Investigations/ Bilirubin conjugated increased/ DIRECT BILIRUBIN INCREASED	29SEP2014 /4	07OCT2014 /-65	C	2	0	1	4[Hcc]	1
	Gastrointestinal disorders/ Abdominal pain lower/ PAIN IN THE LEFT SIDE OF HYPOGASTRIUM	29DEC2014 /95	29DEC2014 /18	C	1	0	1	5[Abdominoc entesis]	1
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	16DEC2014 /82	07JAN2015 /27	C	1	1	1	5[Ascites]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0011/61 /M/A1/Y	Investigations/ Blood bilirubin increased/ TOTAL BILRUBIN INCREASED	20DEC2014 /86	28DEC2014 /17	C	1	1	1	4[Hcc]	2
	Investigations/ Haemoglobin decreased/ HEMOGLOBIN DECREASED	03DEC2014 /69	07JAN2015 /27	C	1	0	1	5[It Is Related To Liver Cancer And Upper Gastrointes tinal Hemorrhage. ]	2
	Investigations/ Blood bilirubin increased/ TOTAL BILRUBIN INCREASED	16DEC2014 /82	20DEC2014 /9	C	2	1	1	4[Hcc]	1
	Investigations/ Haemoglobin decreased/ HEMOGLOBIN DECREASED	30DEC2014 /96	30DEC2014 /19	C	2	1	1	5[Upper Gastrointes tinal Hemorrhage]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0011/61 /M/A1/Y	Investigations/ Blood bilirubin increased/ TOTAL BILRUBIN INCREASED	28DEC2014 /94	07JAN2015 /27	C	1	1	1	4[Hcc]	3
	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	24DEC2014 /90	28DEC2014 /17	C	2	1	1	5[Hcc]	3
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	29SEP2014 /4	15OCT2014 /-57	C	1	0	1	4[Splenomeg aly]	2
	Investigations/ Bilirubin conjugated increased/ DIRECT BILIRUBIN INCREASED	07OCT2014 /12	15OCT2014 /-57	C	2	0	1	4[Hcc]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
501-0011/61 /M/A1/Y	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	16DEC2014 /82	20DEC2014 /9	C	2	1	1	5[Diet]	3
	Investigations/ Blood bilirubin increased/ TOTAL BILIRUBIN INCREASED	07OCT2014 /12	15OCT2014 /-57	C	2	0	1	4[Hcc]	1
	Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	24DEC2014 /90	07JAN2015 /27	C	1	1	1	5[Hcc]	1
502-0001/70 /M/A1/N	Investigations/ Prothrombin time prolonged/ PROTHROMBIN TIME MILDLY INCREASED	03JAN2014 /20	14JAN2014 /4	C	1	0	1	5[CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
502-0001/70 /M/A1/N	Blood and lymphatic system disorders/ Anaemia/ ANAEMIA	20DEC2013 /6	14JAN2014 /4	C	1	0	1	5 [CD]	3
	Investigations/ Alanine aminotransferase increased/ ALANINE AMINOTRANSFERASE INCREASED	03JAN2014 /20	14JAN2014 /4	C	1	1	1	5 [CD]	2
	Investigations/ Platelet count decreased/ PLATELET COUNT DECREASED	20DEC2013 /6	14JAN2014 /4	C	1	0	1	5 [CD]	2
	Gastrointestinal disorders/ Upper gastrointestinal haemorrhage/ UPPER GASTROINTESTINAL HEMORRHAGE	13JAN2014 /30	14JAN2014 /4	C	4	2	1	5 [CD]	5

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
502-0003/48 /M/A1/Y	Gastrointestinal disorders/ Ascites/ ASCITES	05MAY2014 /110	10JUL2014 /97	C	1	1	1	5 [PD]	2
	Hepatobiliary disorders/ Hepatic function abnormal/ ABNORMAL LIVER FUNCTION	26MAY2014 /131	10JUL2014 /97	C	1	1	1	5 [CD]	2
	Investigations/ Bilirubin conjugated increased/ DIRECT BILIRUBIN EXALTATION	05MAY2014 /110	10JUL2014 /97	C	1	1	1	5 [CD]	2
	Investigations/ Blood bilirubin increased/ TOTAL BILIRUBIN EXALTATION	05MAY2014 /110	10JUL2014 /97	C	1	1	1	5 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
502-0003/48 /M/A1/Y	Hepatobiliary disorders/ Hepatic function abnormal/ ABNORMAL LIVER FUNCTION	05MAY2014 /110	26MAY2014 /52	C	1	1	1	5[CD]	1
	Investigations/ Coagulation time abnormal/ COAGULANT FUNCTION ABNORMALITY	05MAY2014 /110	10JUL2014 /97	C	1	0	1	5[Hcc.]	3
	Metabolism and nutrition disorders/ Hyperlipidaemia/ HYPERLIPIDAEMIA	07FEB2014 /23	21FEB2014 /-42	C	1	0	1	2	1
503-0002/71 /F/A1/N	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	17AUG2014 /178	17AUG2014 /-65	I	1	0	1	4[Related To Tumor]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
503-0002/71 /F/A1/N	Investigations/ Blood albumin decreased/ ALBUMIN LOWER	15JUL2014 /145	29JUL2014 /-84	I	1	0	1	4[Related To Tumor]	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMEN PAIN	17AUG2014 /178	17AUG2014 /-65	I	1	1	1	4[Related To Tumor]	2
	Investigations/ Haemoglobin decreased/ LOWER HEMOGLOBIN	20MAY2014 /89	17JUN2014 /-126	C	1	0	1	4[CD]	1
	Investigations/ Haemoglobin decreased/ LOWER HEMOGLOBIN	13MAR2014 /21	18MAY2014 /-156	C	1	0	1	4[CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
503-0002/71 /F/A1/N	General disorders and administration site conditions/ Pyrexia/ FEVER	24MAY2014 /93	27MAY2014 /-147	C	1	0	1	4[The Subject Have A Cold, Did Not Related To The Study Drug.]	1
	Infections and infestations/ Influenza/ INFLUENZA	24MAY2014 /93	27MAY2014 /-147	C	1	0	1	4[The Subject Have A Cold, Did Not Related To The Study Drug.]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
503-0003/47 /F/A1/Y	Gastrointestinal disorders/ Melaena/ MELENA	28MAR2014 /21	01APR2014 /-2	C	1	0	1	4[Related To Liver Cirrhosis, Portal Hypertensio n And Varices, Coagulation Dysfunction ]	2
	Gastrointestinal disorders/ Haematemesis/ HAEMATEMESIS	28MAR2014 /21	29MAR2014 /-5	I	1	1	1	4[CD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
503-0003/47 /F/A1/Y	Metabolism and nutrition disorders/ Hypoglycaemia/ HYPOGLYCEMIA	28MAR2014 /21	Unknown/NA	I	6	0	1	4[Before Screen ,hyp oglycemia Still Exist.]	4
	Gastrointestinal disorders/ Abdominal distension/ ABDOMINAL DISTENSION	07MAR2014 /0	10MAR2014 /-24	C	1	1	1	4[CD]	2
503-0005/72 /M/A1/Y	Investigations/ Aspartate aminotransferase increased/ ASPERTATE AMINOTRANSFERASE INCREASED	15FEB2015 /327	Unknown/NA	C	2	0	1	4[Related To Hcc]	1
	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	15FEB2015 /327	Unknown/NA	C	2	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
503-0005/72 /M/A1/Y	Investigations/ Blood creatinine increased/ CREATININE INCREASED	04FEB2015 /316	Unknown/NA	C	2	0	1	4[Related To Hcc]	1
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	05AUG2014 /133	19AUG2014 /-180	C	2	0	1	4[Related To Tumor]	1
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	10JUN2014 /77	23JUL2014 /-207	C	1	0	1	4[Related To Tumor]	2
	Renal and urinary disorders/ Hyperuricosuria/ HYPERURICOSURIA	24JUN2014 /91	Unknown/NA	I	6	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
503-0005/72 /M/A1/Y	Renal and urinary disorders/ Hyperuricosuria/ HYPERURICOSURIA	27MAY2014 /63	10JUN2014 /-250	I	1	0	1	3	1
	Investigations/ Platelet count decreased/ LOW PLATELET COUNT	10JUN2014 /77	05AUG2014 /-194	C	1	0	1	4[CD]	2
504-0003/53 /M/A1/N	General disorders and administration site conditions/ Pain/ ACHE	14MAR2014 /1	Unknown/NA	I	6	1	1	4[CM]	1
	Investigations/ Blood bilirubin increased/ ELEVATED BILIRUBIN	11APR2014 /29	16MAY2014 /43	C	1	0	1	5[Disease Association ]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
504-0003/53 /M/A1/N	Investigations/ Blood bilirubin increased/ ELEVATED BILIRUBIN	03APR2014 /21	11APR2014 /8	C	2	0	1	5[Disease Association ]	2
	Investigations/ Gamma-glutamyltransferase increased/ INCREASED GGT	11APR2014 /29	16MAY2014 /43	C	1	0	1	5[Disease Association ]	2
	Investigations/ Gamma-glutamyltransferase increased/ INCREASED GGT	03APR2014 /21	11APR2014 /8	C	2	0	1	5[Disease Association ]	1
	Investigations/ Blood alkaline phosphatase increased/ INCREASED ALP	11APR2014 /29	16MAY2014 /43	C	1	0	1	5[Disease Association ]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
504-0003/53 /M/A1/N	Investigations/ Aspartate aminotransferase increased/ INCREASED AST	03APR2014 /21	16MAY2014 /43	C	1	0	1	5[Disease Association ]	1
	Investigations/ Activatedpartialthromboplastin time prolonged/ APTT PROLONGED	20MAR2014 /7	03APR2014 /0	C	1	0	1	5[Disease Association ]	1
	Metabolism and nutrition disorders/ Hypercalcaemia/ HYPERCALCEMIA	03APR2014 /21	11APR2014 /8	I	1	2	1	5[Disease Association ]	4
	Metabolism and nutrition disorders/ Hypercalcaemia/ HYPERCALCEMIA	20MAR2014 /7	03APR2014 /0	C	2	0	1	5[Disease Association ]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
504-0005/41 /F/A1/Y	Investigations/ Prothrombin time prolonged/ PT-SEC PROLONG	24SEP2014 /21	08NOV2014 /30	C	1	0	1	5[Disease Association ]	1
	Investigations/ International normalised ratio increased/ INR PROLONG	24SEP2014 /21	08NOV2014 /30	C	1	0	1	5[Disease Association ]	1
	Investigations/ Activated partial thromboplastin time prolonged/ APTT PROLONG	09OCT2014 /36	08NOV2014 /30	C	1	0	1	5[Disease Association ]	1
	General disorders and administration site conditions/ Disease progression/ DISEASE PROGRESSION	08NOV2014 /66	08NOV2014 /30	C	4	0	1	4[PD]	5

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
506-0001/43 /M/A1/N	Investigations/ Prothrombin time prolonged/ PROTHROMBIN TIME INCREASE	21MAY2014 /36	29JUL2014 /69	C	1	0	1	5 [CD]	1
	Investigations/ Fibrin D dimer increased/ FIBRINOGEN DEGRADATION PRODUCTS INCREASED	06MAY2014 /21	29JUL2014 /69	C	1	0	1	5 [CD]	1
	Investigations/ Fibrin D dimer increased/ D-DIMER INCREASED	06MAY2014 /21	29JUL2014 /69	C	1	0	1	5 [CD]	1
	Investigations/ Blood fibrinogen increased/ FIBRINOGEN INCREASE	06MAY2014 /21	29JUL2014 /69	C	1	0	1	5 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
506-0001/43 /M/A1/N	Investigations/ Blood bilirubin increased/ TOTAL BILIRUBIN INCREASED	21MAY2014 /36	29JUL2014 /69	C	1	0	1	5 [CD]	1
	Blood and lymphatic system disorders/ Anaemia/ ANEMIA	06MAY2014 /21	29JUL2014 /69	C	1	0	1	5 [CD]	1
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE TRANSAEMINASE INCREASED	14MAY2014 /29	29JUL2014 /69	C	1	0	1	5 [CD]	2
	Investigations/ Aspartate aminotransferase increased/ ASPARTATE TRANSAMINASE INCREASE	29APR2014 /14	13MAY2014 /-8	C	1	0	1	5 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
506-0001/43 /M/A1/N	Respiratory, thoracic and mediastinal disorders/ Cough/ COUGH	15MAY2014 /30	29JUL2014 /69	I	1	1	1	5[It Was A New Ae.]	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	17MAY2014 /32	29JUL2014 /69	I	1	1	1	5[CD]	1
506-0005/24 /M/A1/Y	Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	13JAN2015 /22	20JAN2015 /13	C	1	0	1	4[PD]	1
	Investigations/ Blood lactate dehydrogenase increased/ LDH INCREASED	12JAN2015 /21	13JAN2015 /6	C	1	0	1	5[CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
506-0005/24 /M/A1/Y	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	12JAN2015 /21	20JAN2015 /13	C	1	1	1	5 [CD]	3
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	31DEC2014 /9	11JAN2015 /4	C	1	0	1	5 [CD]	2
	Investigations/ Blood bilirubin increased/ BILIRUBIN INCREASED	12JAN2015 /21	13JAN2015 /6	C	1	0	1	5 [CD]	1
	Hepatobiliary disorders/ Hepatic haemorrhage/ HEPATIC HEMORRHAGE	20JAN2015 /29	20JAN2015 /13	C	4	0	3 /13JAN2015 /Unknown	4 [PD]	5

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
506-0005/24 /M/A1/Y	Hepatobiliary disorders/ Hepatic haemorrhage/ HEPATIC HEMORRHAGE	12JAN2015 /21	19JAN2015 /12	C	1	1	2	4[Disease Releated]	2
507-0001/51 /M/A1/Y	Investigations/ Fibrin D dimer increased/ D- DIMER INCREASED	09OCT2014 /77	Unknown/NA	C	2	0	1	5	1
	Investigations/ Total bile acids increased/ THE TOTAL BILE ACID INCREASED	09OCT2014 /77	Unknown/NA	C	2	0	1	5	1
	Investigations/ Blood cholinesterase decreased/ CHOLINESTERASE DECLINE	09SEP2014 /47	Unknown/NA	C	2	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
507-0001/51 /M/A1/Y	Investigations/ Gamma-glutamyltransferase increased/ GGT INCREASED	25SEP2014 /63	Unknown/NA	C	2	1	1	5	1
	Investigations/ Alpha hydroxybutyrate dehydrogenase increased/ ALPHA-HYDROXYBUTYRATE DEHYDROGENASE INCREASED	04SEP2014 /42	11SEP2014 /-28	C	1	0	1	5	1
	Investigations/ Blood cholinesterase decreased/ CHOLINESTERASE DECLINE	11SEP2014 /49	25SEP2014 /-14	C	1	1	1	5	1
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	11SEP2014 /49	25SEP2014 /-14	C	1	1	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
507-0001/51 /M/A1/Y	Investigations/ Blood lactate dehydrogenase increased/ LDH INCREASED	04SEP2014 /42	11SEP2014 /-28	C	1	1	1	5	1
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	11SEP2014 /49	Unknown/NA	C	2	1	1	5	1
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED.	04SEP2014 /42	11SEP2014 /-28	C	2	0	1	5	3
	Investigations/ Blood cholinesterase decreased/ CHOLINESTERASE DECLINE	21AUG2014 /28	28AUG2014 /-42	C	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
507-0001/51 /M/A1/Y	Investigations/ Blood glucose increased/ ELEVATED BLOOD SUGAR	21AUG2014 /28	28AUG2014 /-42	I	1	0	1	3	2
	Investigations/ Plateletcrit decreased/ PLATELETCRIT DECREASED	14AUG2014 /21	28AUG2014 /-42	C	1	0	1	5 [PD]	1
	Investigations/ Gamma-glutamyltransferase increased/ GGT INCREASED	14AUG2014 /21	25SEP2014 /-14	C	2	0	1	5	2
	Investigations/ Platelet count decreased/ PLATELET DECLINE	14AUG2014 /21	28AUG2014 /-42	I	1	0	1	5	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
507-0001/51 /M/A1/Y	Investigations/ Gamma-glutamyltransferase increased/ GGT INCREASED.	31JUL2014 /7	14AUG2014 /-56	C	2	0	1	5	3
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	31JUL2014 /7	07AUG2014 /-63	C	1	0	1	5	1
507-0002/44 /M/A1/Y	Gastrointestinal disorders/ Constipation/ CONSTIPATION	05OCT2014 /68	11OCT2014 /25	I	1	1	1	5 [PD]	1
	Gastrointestinal disorders/ Constipation/ CONSTIPATION	23SEP2014 /56	02OCT2014 /16	I	1	1	1	5 [PD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
507-0002/44 /M/A1/Y	Renal and urinary disorders/ Oliguria/ OLIGURIA	20SEP2014 /53	02OCT2014 /16	C	1	1	1	5 [PD]	1
	Renal and urinary disorders/ Oliguria/ OLIGURIA	16SEP2014 /49	20SEP2014 /4	I	2	1	1	5 [PD]	2
	Metabolism and nutrition disorders/ Decreased appetite/ LOSS OF APPETITE	15OCT2014 /78	10NOV2014 /55	C	1	1	1	5 [PD]	2
	Metabolism and nutrition disorders/ Decreased appetite/ LOSS OF APPETITE	23SEP2014 /56	14OCT2014 /28	I	2	1	1	5 [PD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
507-0002/44 /M/A1/Y	Metabolism and nutrition disorders/ Decreased appetite/ LOSS OF APPETITE	16SEP2014 /49	23SEP2014 /7	I	2	1	1	5 [PD]	2
	General disorders and administration site conditions/ Oedema peripheral/ LOWER EXTREMITY EDEMA	20SEP2014 /53	10NOV2014 /55	C	1	1	1	5 [PD]	1
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	15OCT2014 /78	10NOV2014 /55	C	1	1	1	5 [PD]	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	05OCT2014 /68	14OCT2014 /28	I	2	1	1	5 [PD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
507-0002/44 /M/A1/Y	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	02OCT2014 /65	05OCT2014 /19	I	2	1	1	5 [PD]	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	23SEP2014 /56	02OCT2014 /16	I	2	1	1	5 [PD]	1
	Gastrointestinal disorders/ Abdominal distension/ BLOATING	15OCT2014 /78	10NOV2014 /55	I	1	1	1	5 [PD]	2
	Gastrointestinal disorders/ Abdominal distension/ BLOATING	26SEP2014 /59	14OCT2014 /28	I	2	1	1	5 [PD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
507-0002/44 /M/A1/Y	Gastrointestinal disorders/ Abdominal distension/ BLOATING	16SEP2014 /49	26SEP2014 /10	I	2	1	1	5 [PD]	2
	General disorders and administration site conditions/ Oedema peripheral/ LOWER EXTREMITY EDEMA	16SEP2014 /49	20SEP2014 /4	I	2	1	1	5 [PD]	2
	General disorders and administration site conditions/ Fatigue/ FATIGUE	16SEP2014 /49	10NOV2014 /55	C	1	1	1	5 [PD]	2
	Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	16SEP2014 /49	23SEP2014 /7	I	2	1	1	5 [PD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
507-0002/44 /M/A1/Y	Investigations/ Blood glucose increased/ BLOOD SUGAR INCREASED	21SEP2014 /54	03OCT2014 /17	I	1	0	1	3	1
	Investigations/ Neutrophil count decreased/ NEUTROPHIL DECREASED	10OCT2014 /73	14OCT2014 /28	C	1	1	1	5 [PD]	2
	Investigations/ Neutrophil count decreased/ NEUTROPHIL DECREASED	21SEP2014 /54	28SEP2014 /12	C	1	1	1	5 [PD]	3
	Investigations/ White blood cell count decreased/ WBC DECREASED	10OCT2014 /73	14OCT2014 /28	C	1	1	1	5 [PD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
507-0002/44 /M/A1/Y	Investigations/ White blood cell count decreased/ WBC DECREASED	21SEP2014 /54	28SEP2014 /12	C	1	1	1	5 [PD]	3
	Investigations/ Blood lactate dehydrogenase increased/ LDH INCREASED	16SEP2014 /49	10NOV2014 /55	C	1	1	1	5 [PD]	1
	Investigations/ Total bile acids increased/ THE TOTAL BILE ACID INCREASED	16SEP2014 /49	28SEP2014 /12	C	1	1	1	5 [PD]	1
	Investigations/ Blood alkaline phosphatase increased/ ALP INCREASED	03OCT2014 /66	10NOV2014 /55	C	1	1	1	5 [PD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
507-0002/44 /M/A1/Y	Investigations/ Blood alkaline phosphatase increased/ ALP INCREASED	28SEP2014 /61	03OCT2014 /17	C	2	1	1	5 [PD]	1
	Investigations/ Blood alkaline phosphatase increased/ ALP INCREASED	16SEP2014 /49	28SEP2014 /12	C	2	1	1	5 [PD]	2
	Investigations/ Alpha hydroxybutyrate dehydrogenase increased/ ?- HYDROXYBUTYRATE DEHYDROGENASE INCREASED	16SEP2014 /49	10NOV2014 /55	C	1	1	1	5 [PD]	1
	Investigations/ Bilirubin conjugated increased/ DIRECT BILIRUBIN INCREASED	21SEP2014 /54	10NOV2014 /55	C	1	1	1	5 [PD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
507-0002/44 /M/A1/Y	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	16SEP2014 /49	21SEP2014 /5	C	2	1	1	5 [PD]	3
	Investigations/ Bilirubin conjugated increased/ DIRECT BILIRUBIN INCREASED	16SEP2014 /49	10NOV2014 /55	C	1	1	1	5 [PD]	1
	Investigations/ Blood cholinesterase decreased/ CHOLINESTERASE DECLINE	10OCT2014 /73	10NOV2014 /55	C	1	1	1	5 [PD]	2
	Investigations/ Blood cholinesterase decreased/ CHOLINESTERASE DECLINE	16SEP2014 /49	10OCT2014 /24	C	2	1	1	5 [PD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
507-0002/44 /M/A1/Y	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	14OCT2014 /77	10NOV2014 /55	C	1	1	1	5 [PD]	2
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	21SEP2014 /54	14OCT2014 /28	C	2	1	1	5 [PD]	1
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	16SEP2014 /49	21SEP2014 /5	C	2	1	1	5 [PD]	3
	Investigations/ Haemoglobin decreased/ HEMOGLOBIN DECREASED	03OCT2014 /66	10NOV2014 /55	C	1	1	1	5 [PD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
507-0002/44 /M/A1/Y	Investigations/ Haemoglobin decreased/ HEMOGLOBIN DECREASED	23SEP2014 /56	03OCT2014 /17	C	2	1	1	5 [PD]	2
	Investigations/ Haemoglobin decreased/ HEMOGLOBIN DECREASED	16SEP2014 /49	23SEP2014 /7	C	2	1	1	5 [PD]	3
	Investigations/ Blood bilirubin increased/ TOTAL BILIRUBIN INCREASED	10OCT2014 /73	10NOV2014 /55	C	1	1	1	5 [PD]	3
	Investigations/ Blood bilirubin increased/ TOTAL BILIRUBIN INCREASED	28SEP2014 /61	10OCT2014 /24	C	2	1	1	5 [PD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
507-0002/44 /M/A1/Y	Investigations/ Blood bilirubin increased/ TOTAL BILIRUBIN INCREASED	21SEP2014 /54	28SEP2014 /12	C	2	1	1	5 [PD]	1
	Investigations/ Blood bilirubin increased/ TOTAL BILIRUBIN INCREASED	09SEP2014 /42	21SEP2014 /5	C	2	1	1	5 [PD]	2
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	09SEP2014 /42	16SEP2014 /0	C	2	1	1	3	1
	Investigations/ Blood glucose increased/ ELEVATED BLOOD SUGAR	02SEP2014 /35	09SEP2014 /-7	I	1	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
507-0002/44 /M/A1/Y	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	26AUG2014 /28	16SEP2014 /0	C	2	1	1	3	2
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED.	26AUG2014 /28	09SEP2014 /-7	C	2	1	1	3	2
	Investigations/ Gamma-glutamyltransferase increased/ GGT INCREASED	20AUG2014 /22	14OCT2014 /28	C	2	0	1	3	3
	Investigations/ Platelet count decreased/ PLATELET DECLINE	20AUG2014 /22	02SEP2014 /-14	C	1	0	1	5 [PD]	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
507-0002/44 /M/A1/Y	Investigations/ Neutrophil count decreased/ REDUCED NEUTROPHIL	20AUG2014 /22	02SEP2014 /-14	I	1	0	1	5 [PD]	1
	Investigations/ Neutrophil count decreased/ REDUCED NEUTROPHIL	05AUG2014 /7	20AUG2014 /-27	C	2	1	1	3	2
	Investigations/ White blood cell count decreased/ WBC REDUCE	05AUG2014 /7	02SEP2014 /-14	C	1	1	1	3	2
	General disorders and administration site conditions/ Pyrexia/ FEVER	29JUL2014 /0	29JUL2014 /-49	I	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
507-0002/44 /M/A1/Y	Investigations/ Haemoglobin decreased/ DECREASED HEMOGLOBIN	29JUL2014 /0	20AUG2014 /-27	C	1	0	1	3	1
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	29JUL2014 /0	05AUG2014 /-42	C	1	1	1	3	1
	Investigations/ Alanine aminotransferase increased/ ALT INCREASED	29JUL2014 /0	05AUG2014 /-42	C	1	1	1	3	1
508-0002/64 /M/A1/Y	Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICEMIA	11APR2014 /51	Unknown/NA	C	6	0	1	4[It Is Related To His Progression Disease.]	4

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
508-0002/64 /M/A1/Y	Investigations/ Blood creatinine increased/ CREATININE INCREASE	11APR2014 /51	Unknown/NA	C	6	0	1	4	2
	Investigations/ Blood bilirubin increased/ TBIL INCREASE	11APR2014 /51	Unknown/NA	C	6	0	1	4	2
	Investigations/ Blood lactate dehydrogenase increased/ LDH INCREASE	11APR2014 /51	Unknown/NA	C	6	0	1	4	2
	Investigations/ Gamma-glutamyltransferase increased/ GGT INCREASE	11APR2014 /51	Unknown/NA	C	6	0	1	4	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
508-0002/64 /M/A1/Y	Investigations/ Blood alkaline phosphatase increased/ ALP INCREASE	11APR2014 /51	Unknown/NA	C	6	0	1	4	1
	Investigations/ Alanine aminotransferase increased/ ALT INCREASE	11APR2014 /51	Unknown/NA	C	6	0	1	4	3
	Investigations/ Aspartate aminotransferase increased/ AST INCREASE	11APR2014 /51	Unknown/NA	C	6	0	1	4	1
	Metabolism and nutrition disorders/ Decreased appetite/ APPETITE LOSS	11APR2014 /51	Unknown/NA	C	6	0	1	4	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
508-0002/64 /M/A1/Y	General disorders and administration site conditions/ Asthenia/ FEEBLE	11APR2014 /51	Unknown/NA	C	6	0	1	4	2
	Investigations/ Weight decreased/ WEIGHT LOSS	11APR2014 /51	Unknown/NA	C	6	0	1	4	1
	Gastrointestinal disorders/ Gastrointestinal haemorrhage/ HEMORRHAGE OF DIGESTIVE TRACT	15APR2014 /55	15APR2014 /4	C	4	0	2	4[It Is Related To Renal Failure.]	5
	Gastrointestinal disorders/ Ascites/ ASCITES	24MAR2014 /33	Unknown/NA	C	2	1	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
508-0002/64 /M/A1/Y	Infections and infestations/ Lung infection/ PULMONARY INFECTION	11MAR2014 /20	25MAR2014 /-17	C	1	1	3 /24MAR2014 /31MAR2014	4[It Is Related To Tumor Matastasis Of His Lung.]	3
	General disorders and administration site conditions/ Oedema/ EDEMA	01MAR2014 /10	Unknown/NA	C	2	1	1	5[CD]	1
	Gastrointestinal disorders/ Dry mouth/ XEROSTOMIA	19FEB2014 /0	Unknown/NA	C	6	0	1	1	1
508-0004/58 /M/A1/Y	Investigations/ Blood bilirubin increased/ BILIRUBIN INCREASE	03SEP2014 /7	Unknown/NA	C	6	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
508-0004/58 /M/A1/Y	Vascular disorders/ Hypertension/ HYPERTENSION	03SEP2014 /7	Unknown/NA	C	6	1	1	3	1
	Gastrointestinal disorders/ Ascites/ ASCITES	15SEP2014 /19	Unknown/NA	C	6	0	1	4[It Is Related To Disease Progress.]	2
509-0003/39 /M/A1/N	Infections and infestations/ Bacterial infection/ BACTERIAL INFECTION	14AUG2014 /21	29OCT2014 /20	C	1	0	1	4[CD]	1
	Metabolism and nutrition disorders/ Hypochloraemia/ HYPOCHLOREMIA	09OCT2014 /77	Unknown/NA	C	6	0	1	4[CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
509-0003/39 /M/A1/N	Metabolism and nutrition disorders/ Hyponatraemia/ HYPONATREMIA	09OCT2014 /77	Unknown/NA	C	6	1	1	4 [CD]	1
	Investigations/ Blood lactate dehydrogenase increased/ LDH RISE	31JUL2014 /7	Unknown/NA	C	6	0	1	4 [PD]	1
	Investigations/ Mean cell volume decreased/ MEAN CORPUSCULAR VOLUME REDUCE	25SEP2014 /63	09OCT2014 /0	C	1	0	1	4 [CD]	1
	Investigations/ Haematocrit decreased/ HEMATOCRIT REDUCE	25SEP2014 /63	09OCT2014 /0	C	1	0	1	4 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
509-0003/39 /M/A1/N	Investigations/ Neutrophil count increased/ ABSOLUTE NEUTROPHIL COUNT (ANC) RISE	25SEP2014 /63	Unknown/NA	C	6	0	1	4 [CD]	1
	Investigations/ Neutrophil count increased/ NEUTROPHILS (%) RISE	25SEP2014 /63	Unknown/NA	C	6	0	1	4 [CD]	1
	Investigations/ Platelet count increased/ PLATELET COUNT RISE	25SEP2014 /63	Unknown/NA	C	6	0	1	4 [CD]	1
	Investigations/ Haemoglobin decreased/ HGB REDUCE	25SEP2014 /63	09OCT2014 /0	C	1	0	1	4 [CD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
509-0003/39 /M/A1/N	Investigations/ Red blood cell count decreased/ RBC REDUCE	25SEP2014 /63	09OCT2014 /0	C	1	0	1	4[CD]	1
	Investigations/ White blood cell count increased/ WBC RISE	25SEP2014 /63	Unknown/NA	C	6	0	1	4[CD]	1
	Gastrointestinal disorders/ Abdominal pain/ PAIN IN THE LEFT ABDOMEN.	03SEP2014 /41	Unknown/NA	C	6	0	1	4[PD]	1
	Nervous system disorders/ Hypoaesthesia/ NUMBNESS ON THE RIGHT THIGH	20SEP2014 /58	Unknown/NA	C	6	0	1	4[PD]	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
509-0003/39 /M/A1/N	Psychiatric disorders/ Insomnia/ INSOMNIA	07AUG2014 /14	Unknown/NA	C	6	1	1	3	3
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Neoplasm progression/ TUMOR PROGRESSION	27OCT2014 /95	Unknown/NA	C	6	1	1	5 [PD]	4
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Neoplasm progression/ TUMOR PROGRESSION	27OCT2014 /95	Unknown/NA	C	6	1	1	5 [PD]	3
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to spine/ L2 VERTEBRAL METASTASES	15SEP2014 /53	02OCT2014 /-7	C	3	3	1	4 [CD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
509-0003/39 /M/A1/N	Skin and subcutaneous tissue disorders/ Rash/ RASH	25AUG2014 /32	01SEP2014 /-38	C	1	0	1	4 [CD]	1
	Skin and subcutaneous tissue disorders/ Hyperhidrosis/ HYPERHIDROSIS	04AUG2014 /11	10AUG2014 /-60	C	1	1	1	3	2
	Musculoskeletal and connective tissue disorders/ Back pain/ LUMBAGO	25JUL2014 /1	20SEP2014 /-19	C	2	1	1	5	2
510-0001/67 /M/A1/Y	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	30SEP2014 /216	12NOV2014 /-21	I	1	0	1	1	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
510-0001/67 /M/A1/Y	Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	31JUL2014 /155	Unknown/NA	I	2	1	1	1	1
	Blood and lymphatic system disorders/ Thrombocytopenia/ THROMBOCYTOPENIA	23SEP2014 /209	12NOV2014 /-21	C	1	1	1	3	1
	Blood and lymphatic system disorders/ Leukopenia/ LEUKOPENIA	30SEP2014 /216	12NOV2014 /-21	I	1	0	1	1	1
	Blood and lymphatic system disorders/ Neutropenia/ NEUTROCYTOPENIA	14MAY2014 /77	18MAY2014 /-199	I	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
510-0001/67 /M/A1/Y	Blood and lymphatic system disorders/ Neutropenia/ NEUTROCYTOPENIA	05MAR2014 /7	19MAR2014 /-259	I	1	1	1	4	2
	Blood and lymphatic system disorders/ Leukopenia/ OLIGOLEUKOCYTHEMIA	14MAY2014 /77	18MAY2014 /-199	I	1	1	1	3	2
510-0003/43 /M/A1/Y	General disorders and administration site conditions/ Asthenia/ WEAK	21JUL2014 /46	29JUL2014 /-8	C	1	0	3 /23JUL2014 /30JUL2014	4	2
513-0003/46 /M/A1/N	Respiratory, thoracic and mediastinal disorders/ Epistaxis/ NASAL BLEEDING	10JUN2014 /41	12JUN2014 /36	C	5	2	1	2	

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
513-0003/46 /M/A1/N	Respiratory, thoracic and mediastinal disorders/ Haemoptysis/ HEMOPTYSIS	23MAY2014 /23	12JUN2014 /36	C	4	1	2	4 [PD]	5
	Gastrointestinal disorders/ Upper gastrointestinal haemorrhage/ UPPER GASTROINTESTINAL HEMORRHAGE	11MAY2014 /11	13MAY2014 /6	C	1	1	1	4 [CD]	2
515-0005/45 /M/A1/Y	General disorders and administration site conditions/ Disease progression/ HCC DISEASE PROGRESSION	04OCT2014 /103	04OCT2014 /25	C	4	0	1	5 [PD]	5
	Investigations/ Hepatic enzyme increased/ ELEVATED LIVER ENZYMES	02SEP2014 /71	22SEP2014 /13	C	1	1	1	5 [PD]	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0003/45 /M/A1/Y	Investigations/ Gamma-glutamyltransferase increased/ GGT RISE	30JUL2014 /77	Unknown/NA	C	5	0	1	3	3
	Investigations/ Aspartate aminotransferase increased/ AST RISE	30JUL2014 /77	Unknown/NA	C	5	0	1	3	2
	Investigations/ Blood alkaline phosphatase increased/ ALP RISE	29AUG2014 /107	Unknown/NA	C	5	0	1	4	2
	Investigations/ Lymphocyte count decreased/ THE LYMPHOCYTE ABSOLUTE VALUE DECREASED	30JUL2014 /77	29AUG2014 /30	C	1	0	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0003/45 /M/A1/Y	Investigations/ Blood albumin decreased/ ALBUMIN DECREASED	02JUL2014 /49	29AUG2014 /30	C	1	0	1	3	1
	General disorders and administration site conditions/ Pyrexia/ FEVER	23JUN2014 /40	25JUN2014 /-35	C	1	1	1	4	1
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	18JUN2014 /35	30JUL2014 /0	C	5	0	1	3	1
	Investigations/ Gamma-glutamyltransferase increased/ GGT INCREASED	18JUN2014 /35	30JUL2014 /0	C	5	0	1	3	2

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0003/45 /M/A1/Y	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	04JUN2014 /21	29AUG2014 /30	C	5	0	1	4	1
	Psychiatric disorders/ Irritability/ IRRITABILITY	21MAY2014 /7	21MAY2014 /-70	C	1	1	1	3	1
	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	28MAY2014 /14	04JUN2014 /-56	C	1	0	1	4	2
	Investigations/ Blood alkaline phosphatase increased/ ALKALINE PHOSPHATASE INCREASED	20MAY2014 /6	28MAY2014 /-63	C	6	0	1	4	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015

Listing 16.2.7.1  
Treatment-Emergent Adverse Events  
(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0003/45 /M/A1/Y	Investigations/ Blood albumin decreased/ ALBUMIN DECREASED	20MAY2014 /6	28MAY2014 /-63	C	1	0	1	4	1
	Investigations/ Aspartate aminotransferase increased/ AST INCREASED	20MAY2014 /6	04JUN2014 /-56	C	1	0	1	3	2
	Investigations/ Lymphocyte count decreased/ THE LYMPHOCYTE ABSOLUTE VALUE DECREASED	20MAY2014 /6	04JUN2014 /-56	C	1	0	1	3	1
	Investigations/ White blood cell count decreased/ WHITE BLOOD CELL DECREASED	20MAY2014 /6	04JUN2014 /-56	C	1	1	1	3	1

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015



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(Safety Population)

Treatment Group: Placebo

SubjectNo./ Age[1]/ Gender/ Race[2]/ Anti-Viral use	System Organ Class[3]/ Preferred Term[3]/ Adverse Event	Start Date/ Days from First Dose	Stop Date/ Days from Last Dose	Freq- euncy [4]	Out- come [5]	Tx Req- uired [6]	Action Taken [7]	Rel to Study Tx [8]	CTCAE Grade [9]
517-0010/67 /M/A1/Y	Investigations/ Gamma-glutamyltransferase increased/ GGT RISE	19NOV2014 /7	24MAR2015 /55	C	5	1	1	3	3

Note: Footnotes are listed on page 1.

Executed: 03NOV2015 11:18 Date of Extraction: 23JUL2015