Clinical trial results:
Multicenter, Open-Label Study of Telaprevir in Combination With Peginterferon Alfa and Ribavirin in Human Immunodeficiency Virus/Genotype 1 Chronic Hepatitis C Coinfected Subjects With Severe Fibrosis or Compensated Cirrhosis

Due to the EudraCT – Results system being out of service between 31 July 2015 and 12 January 2016, these results have been published in compliance with revised timelines.

Summary

EudraCT number	2011-003593-85
Trial protocol	BE IT AT DE GB PT HU IE
Global end of trial date	28 August 2014

Results information

Result version number	v1 (current)
This version publication date	20 April 2016
First version publication date	20 April 2016

Trial information

Trial identification

Sponsor protocol code	VX-950HPC3005

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01500616
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen-Cilag International NV
Sponsor organisation address	Antwerpseweg 15-17, B-2340 Beerse, Belgium,
Public contact	Clinical Registry Group, Janssen Cilag International NV, +31 715242166, clinicaltrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Cilag International NV, +31 715242166, clinicaltrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 October 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 August 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this open-label safety study were to provide telaprevir to subjects with human immunodeficiency virus (HIV)/genotype 1 chronic hepatitis C virus (HCV) coinfection with severe fibrosis or compensated cirrhosis who were not eligible for enrollment into an ongoing clinical study of telaprevir, and to collect safety and tolerability data on telaprevir treatment in combination with pegylated interferon (Peg-IFN)-alfa and ribavirin (RBV) in this population.

Protection of trial subjects:

Safety was assessed by monitoring adverse effects (AEs), Serious adverse events (SAEs), Clinical Laboratory Tests (Hematology, Serum Chemistry), HIV Parameters, Vital Sign Measurements, Physical Examination, electrocardiogram (ECG).

Background therapy:

Peginterferon Alfa (Peg-IFN alfa) and Ribavirin (RBV)

Evidence for comparator: -

Actual start date of recruitment	02 May 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 2
Country: Number of subjects enrolled	Germany: 7
Country: Number of subjects enrolled	United Kingdom: 6
Country: Number of subjects enrolled	Hungary: 4
Country: Number of subjects enrolled	Ireland: 2
Country: Number of subjects enrolled	Italy: 49
Country: Number of subjects enrolled	Portugal: 28
Country: Number of subjects enrolled	Russian Federation: 20
Worldwide total number of subjects	118
EEA total number of subjects	98

Notes:

Subjects enrolled per age group

In utero	0

Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	118
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted from 2 May 2012 to 28 August 2014 in 34 sites in 8 countries.

Pre-assignment

Screening details:

In total 186 subjects were screened for this study, out of these 118 subjects were enrolled in study and 107 subjects completed the study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Telaprevir

Arm description:

Subjects received either 750 milligram (mg) or 1125 mg of telaprevir every 8 hour for 12 weeks in combination with Peg-IFN-alfa/Ribavirin during the first 12 weeks of the study. Subjects received Peg-IFN-alfa/Ribavirin for an additional 36 weeks.

Arm type	Experimental
Investigational medicinal product name	Telaprevir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 750 or 1125 mg telaprevir every 8 hours for 12 weeks in combination with pegylated interferon alfa and ribavirin for 48 weeks.

Number of subjects in period 1	Telaprevir
Started	118
Completed	107
Not completed	11
Withdrawal By Subject	5
Other	1
Lost to follow-up	5

Baseline characteristics

Reporting groups	
Reporting group title	Telaprevir
Reporting group description:	
Subjects received either 750 milligram (mg) or 1125 mg of telaprevir every 8 hour for 12 weeks in combination with Peg-IFN-alfa/Ribavirin during the first 12 weeks of the study. Subjects received Peg-IFN-alfa/Ribavirin for an additional 36 weeks.	

Reporting group values	Telaprevir	Total	
Number of subjects	118	118	
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	118	118	
From 65 to 84 years	0	0	
85 years and over	0	0	
Title for AgeContinuous Units: years			
arithmetic mean	44.3		
standard deviation	± 7.93	-	
Title for Gender Units: subjects			
Female	21	21	
Male	97	97	

End points

End points reporting groups

Reporting group title	Telaprevir

Reporting group description:

Subjects received either 750 milligram (mg) or 1125 mg of telaprevir every 8 hour for 12 weeks in combination with Peg-IFN-alfa/Ribavirin during the first 12 weeks of the study. Subjects received Peg-IFN-alfa/Ribavirin for an additional 36 weeks.

Subject analysis set title	Intent-to-treat (ITT) Population
Subject analysis set type	Intention-to-treat

Subject analysis set description:

The intent-to-treat (ITT) population included all enrolled subjects who received at least one dose of telaprevir.

Primary: Percentage of Subjects With Sustained Virologic Response (SVR) (Actual): Snapshot

End point title	Percentage of Subjects With Sustained Virologic Response (SVR) (Actual): Snapshot[1]

End point description:

SVR24 is defined as achieving sustained virologic response 24 weeks after the last dose of HCV drugs. SVR24 (actual) Snapshot is defined as having HCV RNA below the threshold at the last non-missing measurement in the Week 24 Follow-up visit window. Threshold for SVR24 (actual) Snapshot was less than (<) lower limit of Quantification (LLOQ), that is less than 25 international units per milliliter (IU/mL).

End point type	Primary

End point timeframe:

Baseline up to 24 weeks after study drug administration

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not performed for this endpoint.

End point values	Telaprevir			
Subject group type	Reporting group			
Number of subjects analysed	118[2]			
Units: Percentage of participants				
number (not applicable)	66.1			

Notes:

[2] - ITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Sustained Virologic Response (SVR) (Actual): Classic

End point title	Percentage of Subjects With Sustained Virologic Response (SVR) (Actual): Classic[3]

End point description:

SVR24actual (Classic) is defined as having HCV RNA '<LLOQ, target not detected' at End of treatment and having at least one non missing HCV RNA measurement in the Week 24 Follow-up visit window, and not having relapsed, and having completed treatment (all HCV drugs) or having permanently discontinued at least one of the HCV drugs but for a reason other than virologic failure.

End point type	Primary

End point timeframe:

Baseline up to 24 weeks after study drug administration

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not performed for this endpoint.

End point values	Telaprevir			
Subject group type	Reporting group			
Number of subjects analysed	118[4]			
Units: Percentage of Subjects				
number (not applicable)	64.4			

Notes:

[4] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Rapid Virologic Response (RVR) and Extended Rapid Virologic Response (eRVR)

End point title	Percentage of Subjects with Rapid Virologic Response (RVR) and Extended Rapid Virologic Response (eRVR)

End point description:

RVR and eRVR is defined as percentage of subjects having virologic response (<25 IU/mL) at Week 4 and Weeks 4 and 12 of treatment, respectively.

End point type	Secondary

End point timeframe:

Week 4 and 12

End point values	Telaprevir			
Subject group type	Reporting group			
Number of subjects analysed	118[5]			
Units: Percentage of subjects				
number (not applicable)				
RVR	72.9			
eRVR	70.3			

Notes:

[5] - ITT population

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Virologic Response

End point title	Time to Virologic Response

End point description:

The time of first Virologic response was reported. Virologic response was determined using the following threshold: HCV RNA <25 IU/mL.

End point type	Secondary

End point timeframe:

Baseline up to first virologic response

End point values	Telaprevir			
Subject group type	Reporting group			
Number of subjects analysed	118[6]			
Units: Days				
arithmetic mean (standard error)	45.9 (± 3.7)			

Notes:

[6] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Relapse

End point title	Percentage of Subjects with Relapse

End point description:

Relapse was defined as having HCV RNA <LLOQ or '<LLOQ, target not detected' at EOT and HCV RNA detectable during the follow-up phase (and not achieving SVR24 [actual]).

End point type	Secondary

End point timeframe:

Baseline up to End of treatment

End point values	Telaprevir			
Subject group type	Reporting group			
Number of subjects analysed	91			
Units: percentage of subjects				
number (not applicable)	7.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects With Viral Breakthrough

End point title	Percentage of subjects With Viral Breakthrough

End point description:

Viral breakthrough was defined as having a confirmed increase >1 log10 in HCV RNA level from the lowest level reached during the considered treatment phase up to the considered time point, if the

lowest level reached was >LLOQ, or a confirmed value of HCV RNA >100 IU/mL in subjects whose HCV RNA had previously become <LLOQ (detectable or 'target not detected') during the considered treatment phase.

End point type	Secondary

End point timeframe:

Baseline up to End of Treatment

End point values	Telaprevir			
Subject group type	Reporting group			
Number of subjects analysed	118[7]			
Units: Percentage of subjects				
number (not applicable)				
During telaprevir treatment	5.1			
After telaprevir treatment	9.3			

Notes:

[7] - ITT population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point title	Percentage of Subjects With Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point description:

An AE is any untoward medical occurrence in a participant participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. An SAE is any AE that results in: death, persistent or significant disability/incapacity, requires inpatient hospitalization or prolongation of existing hospitalization, is a life-threatening experience, is a congenital anomaly/birth defect and may jeopardize participant and/or may require medical or surgical intervention to prevent one of the outcomes listed above.

End point type	Secondary

End point timeframe:

First telaprevir intake and ended up to last telaprevir intake + 1 day

End point values	Telaprevir			
Subject group type	Reporting group			
Number of subjects analysed	118[8]			
Units: Percentage of Participants				
number (not applicable)				
With any Adverse event (AE)	81.4			
With any Serious Adverse Event (SAE)	9.3			

Notes:

[8] - ITT Population

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

First telaprevir intake and ended up to last telaprevir intake + 1 day

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	14.1

Reporting groups

Reporting group title	Telaprevir

Reporting group description:

Subjects received either 750 milligram (mg) or 1125 mg of telaprevir every 8 hour for 12 weeks in combination with Peg-IFN-alfa/Ribavirin during the first 12 weeks of the study. Subjects received Peg-IFN-alfa/Ribavirin for an additional 36 weeks.

Serious adverse events	Telaprevir		
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 118 (9.32%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 118 (1.69%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	2 / 118 (1.69%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	2 / 118 (1.69%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
General Physical Health Deterioration			

subjects affected / exposed	1 / 118 (0.85%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	5 / 118 (4.24%)		
occurrences causally related to treatment / all	3 / 5		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Depressed Mood			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Renal Impairment			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Arthralgia			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Gastroenteritis			

subjects affected / exposed	1 / 118 (0.85%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Viral Infection			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hypophosphataemia			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hypokalaemia			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Telaprevir		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	95 / 118 (80.51%)		
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Hypertension			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	2		
Pallor			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Surgical and medical procedures			
Astringent Therapy			

subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	15 / 118 (12.71%)		
occurrences (all)	17		
Influenza Like Illness			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Hyperpyrexia			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	2		
Fatigue			
subjects affected / exposed	6 / 118 (5.08%)		
occurrences (all)	6		
Hernia			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	6 / 118 (5.08%)		
occurrences (all)	6		
Injection Site Reaction			
subjects affected / exposed	2 / 118 (1.69%)		
occurrences (all)	2		
Oedema Peripheral			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Abnormal Dreams			

subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Apathy			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Depression			
subjects affected / exposed	4 / 118 (3.39%)		
occurrences (all)	4		
Insomnia			
subjects affected / exposed	2 / 118 (1.69%)		
occurrences (all)	2		
Sleep Disorder			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Suicidal Ideation			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	6 / 118 (5.08%)		
occurrences (all)	6		
Aspartate Aminotransferase Increased			
subjects affected / exposed	3 / 118 (2.54%)		
occurrences (all)	3		
Blood Bilirubin Increased			
subjects affected / exposed	17 / 118 (14.41%)		
occurrences (all)	27		
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Electrocardiogram Qt Prolonged			
subjects affected / exposed	2 / 118 (1.69%)		
occurrences (all)	2		
Blood Creatinine Increased			

subjects affected / exposed	2 / 118 (1.69%)		
occurrences (all)	5		
Blood Phosphorus Decreased			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Blood Uric Acid Increased			
subjects affected / exposed	4 / 118 (3.39%)		
occurrences (all)	8		
Neutrophil Count Decreased			
subjects affected / exposed	2 / 118 (1.69%)		
occurrences (all)	3		
Heart Rate Increased			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Haemoglobin Decreased			
subjects affected / exposed	8 / 118 (6.78%)		
occurrences (all)	11		
Platelet Count Decreased			
subjects affected / exposed	13 / 118 (11.02%)		
occurrences (all)	17		
Gamma-Glutamyltransferase Increased			
subjects affected / exposed	5 / 118 (4.24%)		
occurrences (all)	7		
Transaminases Increased			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Weight Decreased			
subjects affected / exposed	3 / 118 (2.54%)		
occurrences (all)	4		
White Blood Cell Count Decreased			
subjects affected / exposed	2 / 118 (1.69%)		
occurrences (all)	2		
Injury, poisoning and procedural complications			

Wound			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Post-Traumatic Pain			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Cardiac disorders			
Palpitations			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Tachycardia			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Nervous system disorders			
Headache			
subjects affected / exposed	5 / 118 (4.24%)		
occurrences (all)	5		
Dysgeusia			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Dizziness			
subjects affected / exposed	2 / 118 (1.69%)		
occurrences (all)	2		
Myasthenic Syndrome			
subjects affected / exposed	2 / 118 (1.69%)		
occurrences (all)	2		
Neuropathy Peripheral			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	2 / 118 (1.69%)		
occurrences (all)	5		
Anaemia			
subjects affected / exposed	28 / 118 (23.73%)		
occurrences (all)	40		
Hypergammaglobulinaemia			

subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Neutropenia			
subjects affected / exposed	13 / 118 (11.02%)		
occurrences (all)	35		
Thrombocytopenia			
subjects affected / exposed	21 / 118 (17.80%)		
occurrences (all)	26		
Pancytopenia			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Eye disorders			
Conjunctivitis			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Dry Eye			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Visual Impairment			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Gastrointestinal disorders			
Anal Pruritus			
subjects affected / exposed	6 / 118 (5.08%)		
occurrences (all)	7		
Abdominal Discomfort			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Abdominal Pain Upper			
subjects affected / exposed	2 / 118 (1.69%)		
occurrences (all)	2		
Anorectal Discomfort			
subjects affected / exposed	3 / 118 (2.54%)		
occurrences (all)	3		
Gastrooesophageal Reflux Disease			

subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Dry Mouth			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Diarrhoea			
subjects affected / exposed	8 / 118 (6.78%)		
occurrences (all)	10		
Cheilitis			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Oral Disorder			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Nausea			
subjects affected / exposed	11 / 118 (9.32%)		
occurrences (all)	12		
Haemorrhoids			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Haematochezia			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Gingivitis			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	3 / 118 (2.54%)		
occurrences (all)	4		
Proctalgia			
subjects affected / exposed	5 / 118 (4.24%)		
occurrences (all)	5		
Stomatitis			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Hepatobiliary disorders			

Jaundice			
subjects affected / exposed	3 / 118 (2.54%)		
occurrences (all)	3		
Hyperbilirubinaemia			
subjects affected / exposed	5 / 118 (4.24%)		
occurrences (all)	9		
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Eczema			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Erythema			
subjects affected / exposed	3 / 118 (2.54%)		
occurrences (all)	3		
Hyperhidrosis			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Pruritus			
subjects affected / exposed	11 / 118 (9.32%)		
occurrences (all)	13		
Pruritus Generalised			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	19 / 118 (16.10%)		
occurrences (all)	23		
Skin Lesion			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Rash Macular			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Renal and urinary disorders			

Haematuria			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Proteinuria			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Leukocyturia			
subjects affected / exposed	2 / 118 (1.69%)		
occurrences (all)	2		
Endocrine disorders			
Hyperparathyroidism			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Bursitis			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Myalgia			
subjects affected / exposed	3 / 118 (2.54%)		
occurrences (all)	3		
Back Pain			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Neck Pain			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Arthralgia			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Bacteriuria			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		

Anal Abscess			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Dermatophytosis			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Respiratory Tract Infection			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Pharyngitis			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Infected Bites			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Urinary Tract Infection			
subjects affected / exposed	2 / 118 (1.69%)		
occurrences (all)	2		
Respiratory Tract Infection Viral			
subjects affected / exposed	2 / 118 (1.69%)		
occurrences (all)	2		
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Hypophosphataemia			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Hypokalaemia			

subjects affected / exposed	2 / 118 (1.69%)		
occurrences (all)	2		
Hypocalcaemia			
subjects affected / exposed	1 / 118 (0.85%)		
occurrences (all)	1		
Hyperuricaemia			
subjects affected / exposed	2 / 118 (1.69%)		
occurrences (all)	3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 May 2012	The amendment was created mainly because drug-drug interaction (DDI) data that became available indicated that dose adjustment was not considered necessary when co administering etravirine (ETR) or rilpivirine (RPV) with telaprevir. Consequently, subjects on an ETR or RPV-based highly-active antiretroviral therapy (HAART) were allowed to enter the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported