



Clinical trial results:

Open-Label, Phase 3b Study to Determine Efficacy and Safety of Telaprevir, Pegylated-Interferon-alfa-2a and Ribavirin in Hepatitis C Virus Treatment-Naïve and Treatment-Experienced Subjects with Geno type 1 Chronic Hepatitis C and Human Immunodeficiency Virus Type 1 (HCV-1/HIV-1) Coinfection.

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2011-004928-35
Trial protocol	SE GB ES PL
Global end of trial date	03 June 2014

Results information

Result version number	v2 (current)
This version publication date	23 June 2016
First version publication date	02 August 2015
Version creation reason	• Correction of full data set Review of data

Trial information

Trial identification

Sponsor protocol code	VX-950HPC3008
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01513941
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen-Cilag International NV
Sponsor organisation address	Turnhoutseweg 30, Beerse, Belgium, B-2340
Public contact	Clinical Registry Group, Janssen-Cilag International NV, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen-Cilag International NV, 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	03 June 2014
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	03 June 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to assess the antiviral efficacy of telaprevir, pegylated interferon (Peg-IFN)-alfa-2a, and ribavirin (RBV) in hepatitis C virus genotype 1 (HCV-1)/human immunodeficiency virus type 1 (HIV-1)-coinfected subjects as measured by sustained virologic response (SVR12planned), defined as having plasma HCV ribonucleic acid (RNA) levels <25 IU/mL 12 weeks after the last planned dose of HCV study drugs.

Protection of trial subjects:

The safety assessments included Adverse events (AEs), Electrocardiogram (ECG) data, Clinical laboratory tests, Hematology, Coagulation Panel, Biochemistry, Urinalysis, Pregnancy tests and vital signs were monitored throughout the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 March 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	Australia: 11
Country: Number of subjects enrolled	Brazil: 29
Country: Number of subjects enrolled	Spain: 48
Country: Number of subjects enrolled	France: 9
Country: Number of subjects enrolled	United Kingdom: 23
Country: Number of subjects enrolled	Poland: 18
Country: Number of subjects enrolled	Russian Federation: 20
Country: Number of subjects enrolled	Sweden: 4
Worldwide total number of subjects	162
EEA total number of subjects	102

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)	160
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Up to 263 Participants were Screened into the study. Of these, 162 participants were treated.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Treatment Naive

Arm description:

Participants taking one of the permitted HAART regimens for HIV and HCV treatment-naïve defined as subjects who had not received any previous treatment with any approved or investigational drug or drug regimen for the treatment of hepatitis C.

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

Dosage and administration details:

Participants received 750 milligram [mg] every 8 hours [q8h], up to week 12 or if the HAART regimen was Efavirenz-based 1125 mg q8h for 12 weeks of film-coated tablet for oral administration.

Investigational medicinal product name	Pegasys
Investigational medicinal product code	
Other name	Peg-IFN-alfa-2a
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 180-microgram (µg) solution for subcutaneous injection in a prefilled syringe per week up to 48 weeks.

Investigational medicinal product name	Copegus
Investigational medicinal product code	
Other name	ribavirin (RBV)
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 800 milligram per Day (mg/day) up to 48 weeks of film-coated tablet for oral administration.

Arm title	Treatment Experienced
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Arm description:

Participants taking one of the permitted HAART regimens for HIV and HCV-treatment -experienced defined as presence of prior treatment with Pegylated-Interferon-alfa-2a and Ribavirin in Hepatitis C Virus (HCV).

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

Dosage and administration details:

Participants received 750 milligram [mg] every 8 hours [q8h], up to week 12 or if the HAART regimen was Efavirenz-based 1125 mg q8h for 12 weeks of film-coated tablet for oral administration.

Investigational medicinal product name	Pegasys
Investigational medicinal product code	
Other name	Peg-IFN-alfa-2a
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 180-microgram (µg) solution for subcutaneous injection in a prefilled syringe per week up to 48 weeks.

Investigational medicinal product name	Copegus
Investigational medicinal product code	
Other name	Ribavirin (RBV)
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 800 milligram per Day (mg/day) up to 48 weeks of film-coated tablet for oral administration.

Number of subjects in period 1	Treatment Naive	Treatment Experienced
Started	64	98
Completed	53	81
Not completed	11	17
Consent withdrawn by subject	3	9
Adverse event, non-fatal	1	-
Other	2	5
Lost to follow-up	5	3

Baseline characteristics

Reporting groups

Reporting group title	Treatment Naive
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Reporting group description:

Participants taking one of the permitted HAART regimens for HIV and HCV treatment-naïve defined as subjects who had not received any previous treatment with any approved or investigational drug or drug regimen for the treatment of hepatitis C.

Reporting group title	Treatment Experienced
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Reporting group description:

Participants taking one of the permitted HAART regimens for HIV and HCV-treatment -experienced defined as presence of prior treatment with Pegylated-Interferon-alfa-2a and Ribavirin in Hepatitis C Virus (HCV).

Reporting group values	Treatment Naive	Treatment Experienced	Total
Number of subjects	64	98	162
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	63	97	160
From 65 to 84 years	1	1	2
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	42.1	46.9	
standard deviation	± 8.64	± 7.96	-
Title for Gender Units: subjects			
Female	13	22	35
Male	51	76	127

End points

End points reporting groups

Reporting group title	Treatment Naive
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Reporting group description:

Participants taking one of the permitted HAART regimens for HIV and HCV treatment-naïve defined as subjects who had not received any previous treatment with any approved or investigational drug or drug regimen for the treatment of hepatitis C.

Reporting group title	Treatment Experienced
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Reporting group description:

Participants taking one of the permitted HAART regimens for HIV and HCV-treatment -experienced defined as presence of prior treatment with Pegylated-Interferon-alfa-2a and Ribavirin in Hepatitis C Virus (HCV).

Subject analysis set title	Prior Relapsers
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Participants had undetectable HCV RNA at the end of previous treatment (between 8 weeks prior to and 6 weeks after the last dose of HCV medication) but had not achieved sustained virologic response (SVR).

Subject analysis set title	Prior Non-responders
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Subject failed to have decrease in hepatitis C virus (HCV) ribonucleic acid (RNA) by greater than (>) 2 log10 after approximately 12 weeks of previous HCV therapy

Primary: Percentage of participants achieving sustained virologic response (SVR) 12 planned

End point title	Percentage of participants achieving sustained virologic response (SVR) 12 planned ^[1]
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End point description:

Sustained virologic response (SVR) planned defined as having plasma HCV RNA levels <25 IU/mL 12 weeks after the last planned dose of HCV study drugs.

End point type	Primary
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End point timeframe:

60 weeks

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: Descriptive statistics were done, no inferential statistical analyses were performed

End point values	Treatment Naive	Treatment Experienced	Prior Relapsers	Prior Non-responders
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	64	98	29	69
Units: Percentage				
number (confidence interval 95%)	64.1 (51.1 to 75.7)	53.1 (42.7 to 63.2)	62.1 (42.3 to 79.3)	49.3 (37 to 61.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Extended Rapid Virologic Response (eRVR)

End point title	Percentage of Participants with Extended Rapid Virologic Response (eRVR)
End point description: Extended Rapid Virologic Response (eRVR) is defined as having plasma Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) levels Less than (<) 25 IU/mL, target not detected at Week 4 and Week 12 of treatment.	
End point type	Secondary
End point timeframe: Week 4 and week 12	

End point values	Treatment Naive	Treatment Experienced	Prior Relapsers	Prior Non-responders
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	64	98	29	69
Units: Percentage				
number (confidence interval 95%)	57.8 (44.8 to 70.1)	43.9 (33.9 to 54.3)	48.3 (29.4 to 67.5)	42 (30.2 to 54.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Relapse

End point title	Percentage of Participants with Relapse
End point description: Relapse having confirmed detectable plasma hepatitis C virus (HCV) ribonucleic acid (RNA) from planned end of treatment (i.e., Week 24 or Week 48) onwards after previous HCV RNA <25 IU/mL at planned end of HCV treatment, and not achieving sustained virologic response rates 12 weeks after the last (planned) dose of HCV study drugs (SVR12 planned).	
End point type	Secondary
End point timeframe: Week 48 up to Week 60	

End point values	Treatment Naive	Treatment Experienced	Prior Relapsers	Prior Non-responders
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	45	56	19	37
Units: Percentage				
number (not applicable)	8.9	7.1	5.3	8.1

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with viral breakthrough

End point title	Number of participants with viral breakthrough
End point description: Viral breakthrough was defined as having a confirmed increase greater than (>) 1 log ₁₀ in hepatitis C virus (HCV) RNA level from the lowest level reached during a considered treatment phase or a confirmed value of hepatitis C virus (HCV) ribonucleic acid(RNA) greater than (>) 100 international unit per millilitre (IU/mL) in participants whose hepatitis C virus (HCV) ribonucleic acid (RNA) level had previously become greater than (>) 25 international unit per millilitre (IU/mL) during the considered treatment phase.	
End point type	Secondary
End point timeframe: Baseline (Week 1) up to Week 24/48	

End point values	Treatment Naive	Treatment Experienced	Prior Relapsers	Prior Non-responders
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	64	98	29	69
Units: Percentage				
number (not applicable)	14.1	18.4	3.4	24.6

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants achieving sustained virologic response (SVR) 24 planned

End point title	Number of participants achieving sustained virologic response (SVR) 24 planned
End point description: SVR24planned, defined as having plasma Hepatitis C Virus (HCV) ribonucleic acid (RNA) levels less than (<) 25 international unit per millilitre (IU/mL) 24 weeks after the last planned dose of HCV study drugs.	
End point type	Secondary
End point timeframe: 72 weeks	

End point values	Treatment Naive	Treatment Experienced	Prior Relapsers	Prior Non-responders
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	64	98	29	69
Units: Percentage				
number (not applicable)	64.1	54.1	65.5	49.3

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants having plasma Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) levels less than (<) 25 international unit per millilitre (IU/mL), target not detected at the planned end of treatment

End point title	Percentage of participants having plasma Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) levels less than (<) 25 international unit per millilitre (IU/mL), target not detected at the planned end of treatment
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End point description:

Proportion of participants having less than 25 IU/mL at the planned end of treatment (ie, Week 24 or Week 48).

End point type	Secondary
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End point timeframe:

Up to 48 weeks

End point values	Treatment Naïve	Treatment Experienced	Prior Relapsers	Prior Non-responders
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	64	98	29	69
Units: Percentage				
number (not applicable)	79.7	70.4	91.3	62.1

Statistical analyses

No statistical analyses for this end point

Secondary: Participants with on-treatment virologic failure

End point title	Participants with on-treatment virologic failure
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End point description:

Virologic failure (ie, Participants who met a virologic stopping rule and/or met the definition of viral breakthrough).

End point type	Secondary
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End point timeframe:

Baseline (Week 1) up to Week 24/48

End point values	Treatment Naive	Treatment Experienced	Prior Relapsers	Prior Non-responders
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	64	98	29	69
Units: Percentage				
number (not applicable)	21.9	27.6	3.4	37.7

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Upto 4 weeks after the last intake of hepatitis C virus (HCV) study drugs.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	14.1
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Reporting groups

Reporting group title	TREATMENT NAIVE
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Reporting group description:

Subjects who were not given treatment previously.

Reporting group title	TREATMENT EXPERIENCED
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Reporting group description:

Subjects who were given treatment previously.

Serious adverse events	TREATMENT NAIVE	TREATMENT EXPERIENCED	
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 64 (15.63%)	12 / 98 (12.24%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate Cancer Metastatic			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 64 (0.00%)	1 / 98 (1.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Animal Bite			
subjects affected / exposed	1 / 64 (1.56%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Angina Pectoris			

subjects affected / exposed	1 / 64 (1.56%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle Branch Block Right			
subjects affected / exposed	1 / 64 (1.56%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Convulsion			
subjects affected / exposed	1 / 64 (1.56%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 64 (3.13%)	3 / 98 (3.06%)	
occurrences causally related to treatment / all	2 / 2	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 64 (0.00%)	1 / 98 (1.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Non-Cardiac Chest Pain			
subjects affected / exposed	1 / 64 (1.56%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	1 / 64 (1.56%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			

subjects affected / exposed	0 / 64 (0.00%)	1 / 98 (1.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis Acute			
subjects affected / exposed	0 / 64 (0.00%)	1 / 98 (1.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 64 (0.00%)	1 / 98 (1.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Biliary Colic			
subjects affected / exposed	1 / 64 (1.56%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	1 / 64 (1.56%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	0 / 64 (0.00%)	1 / 98 (1.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	1 / 64 (1.56%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Infiltration			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 64 (0.00%)	1 / 98 (1.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Embolism			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 64 (1.56%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	1 / 64 (1.56%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	0 / 64 (0.00%)	1 / 98 (1.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchopneumonia			
subjects affected / exposed	0 / 64 (0.00%)	1 / 98 (1.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	0 / 64 (0.00%)	1 / 98 (1.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	1 / 64 (1.56%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 64 (0.00%)	1 / 98 (1.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Respiratory Tract Infection			
subjects affected / exposed	1 / 64 (1.56%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 64 (0.00%)	1 / 98 (1.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 64 (0.00%)	1 / 98 (1.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Malnutrition			
subjects affected / exposed	1 / 64 (1.56%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	TREATMENT NAIVE	TREATMENT EXPERIENCED	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	62 / 64 (96.88%)	93 / 98 (94.90%)	
Investigations			
Weight Decreased			
subjects affected / exposed	6 / 64 (9.38%)	7 / 98 (7.14%)	
occurrences (all)	8	8	
Nervous system disorders			
Dysgeusia			
subjects affected / exposed	5 / 64 (7.81%)	5 / 98 (5.10%)	
occurrences (all)	5	5	
Dizziness			

subjects affected / exposed occurrences (all)	5 / 64 (7.81%) 6	5 / 98 (5.10%) 5	
Headache subjects affected / exposed occurrences (all)	15 / 64 (23.44%) 23	17 / 98 (17.35%) 18	
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	11 / 64 (17.19%) 22	19 / 98 (19.39%) 32	
Leukopenia subjects affected / exposed occurrences (all)	4 / 64 (6.25%) 10	3 / 98 (3.06%) 6	
Neutropenia subjects affected / exposed occurrences (all)	9 / 64 (14.06%) 17	15 / 98 (15.31%) 36	
Thrombocytopenia subjects affected / exposed occurrences (all)	8 / 64 (12.50%) 12	19 / 98 (19.39%) 34	
General disorders and administration site conditions			
Asthenia subjects affected / exposed occurrences (all)	12 / 64 (18.75%) 14	22 / 98 (22.45%) 26	
Influenza Like Illness subjects affected / exposed occurrences (all)	13 / 64 (20.31%) 18	28 / 98 (28.57%) 32	
Fatigue subjects affected / exposed occurrences (all)	25 / 64 (39.06%) 29	21 / 98 (21.43%) 23	
Irritability subjects affected / exposed occurrences (all)	13 / 64 (20.31%) 14	9 / 98 (9.18%) 9	
Pyrexia subjects affected / exposed occurrences (all)	12 / 64 (18.75%) 16	13 / 98 (13.27%) 17	
Gastrointestinal disorders			

Anal Pruritus			
subjects affected / exposed	15 / 64 (23.44%)	13 / 98 (13.27%)	
occurrences (all)	15	18	
Anorectal Discomfort			
subjects affected / exposed	2 / 64 (3.13%)	6 / 98 (6.12%)	
occurrences (all)	2	8	
Diarrhoea			
subjects affected / exposed	15 / 64 (23.44%)	14 / 98 (14.29%)	
occurrences (all)	25	17	
Dry Mouth			
subjects affected / exposed	5 / 64 (7.81%)	4 / 98 (4.08%)	
occurrences (all)	5	4	
Dyspepsia			
subjects affected / exposed	2 / 64 (3.13%)	7 / 98 (7.14%)	
occurrences (all)	2	8	
Nausea			
subjects affected / exposed	16 / 64 (25.00%)	17 / 98 (17.35%)	
occurrences (all)	17	24	
Haemorrhoids			
subjects affected / exposed	4 / 64 (6.25%)	6 / 98 (6.12%)	
occurrences (all)	5	7	
Vomiting			
subjects affected / exposed	7 / 64 (10.94%)	9 / 98 (9.18%)	
occurrences (all)	12	11	
Proctalgia			
subjects affected / exposed	5 / 64 (7.81%)	0 / 98 (0.00%)	
occurrences (all)	7	0	
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	4 / 64 (6.25%)	7 / 98 (7.14%)	
occurrences (all)	5	13	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 64 (7.81%)	7 / 98 (7.14%)	
occurrences (all)	5	7	
Skin and subcutaneous tissue disorders			

Alopecia subjects affected / exposed occurrences (all)	4 / 64 (6.25%)	5 / 98 (5.10%)	
	4	7	
Dry Skin subjects affected / exposed occurrences (all)	14 / 64 (21.88%)	9 / 98 (9.18%)	
	15	13	
Pruritus subjects affected / exposed occurrences (all)	35 / 64 (54.69%)	41 / 98 (41.84%)	
	50	51	
Rash subjects affected / exposed occurrences (all)	20 / 64 (31.25%)	24 / 98 (24.49%)	
	23	31	
Psychiatric disorders			
Anxiety subjects affected / exposed occurrences (all)	2 / 64 (3.13%)	10 / 98 (10.20%)	
	2	11	
Depressed Mood subjects affected / exposed occurrences (all)	4 / 64 (6.25%)	5 / 98 (5.10%)	
	4	6	
Depression subjects affected / exposed occurrences (all)	7 / 64 (10.94%)	9 / 98 (9.18%)	
	8	9	
Insomnia subjects affected / exposed occurrences (all)	14 / 64 (21.88%)	19 / 98 (19.39%)	
	16	27	
Sleep Disorder subjects affected / exposed occurrences (all)	2 / 64 (3.13%)	7 / 98 (7.14%)	
	2	7	
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	4 / 64 (6.25%)	6 / 98 (6.12%)	
	5	8	
Bone Pain subjects affected / exposed occurrences (all)	4 / 64 (6.25%)	1 / 98 (1.02%)	
	4	1	
Back Pain			

subjects affected / exposed occurrences (all)	1 / 64 (1.56%) 1	6 / 98 (6.12%) 6	
Myalgia subjects affected / exposed occurrences (all)	14 / 64 (21.88%) 14	7 / 98 (7.14%) 8	
Pain in Extremity subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	5 / 98 (5.10%) 6	
Infections and infestations Onychomycosis subjects affected / exposed occurrences (all)	4 / 64 (6.25%) 4	0 / 98 (0.00%) 0	
Metabolism and nutrition disorders Decreased Appetite subjects affected / exposed occurrences (all)	17 / 64 (26.56%) 19	9 / 98 (9.18%) 11	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
31 August 2012	The overall reason for the amendment was to include the following changes: To change the planned number of Participants enrolled per subgroup of the study population, To change the primary analysis` to a snapshot analysis. The snapshot analyses has been accepted by the European Medicines Agency and Food and Drug Administration for previous telaprevir Phase 3 studies and To revise some of the eligibility criteria.
14 May 2013	The overall reason for the amendment was to include the following changes: To revise (disallowed) concomitant drugs in line with IB Edition 14 and IB Edition 14, Addendum 2, and To clarify that switching of a highly-active antiretroviral therapy (HAART) regimen to another regimen could occur if deemed necessary by the investigator.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported