Clinical trial results:
Open-Label, Phase 3b Study To Determine Efficacy and Safety of Telaprevir, Pegylated-Interferon-alfa-2a and Ribavirin in Hepatitis C Genotype 1 Infected, Stable Liver Transplant Subjects

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

Summary

EudraCT number	2011-004724-35
Trial protocol	DE ES GB IT AT BE
Global end of trial date	15 July 2014

Results information

Result version number	v2 (current)
This version publication date	16 July 2016
First version publication date	31 July 2015
Version creation reason	• Correction of full data set Review of data

Trial information

Trial identification

Sponsor protocol code	VX-950HPC3006

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01571583
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen-Cilag International NV
Sponsor organisation address	Turnhoutseweg 30, 2340 Beerse, Belgium,
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	15 July 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 July 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the efficacy of telaprevir administered as 750 milligram (mg) every 8 hours (q8h) in combination with pegylated interferon (Peg-IFN)-alfa-2a and ribavirin (RBV) in genotype 1 chronic HCV infected liver transplant patients as measured by sustained virologic response SVR12planned. SVR12planned is defined as having HCV RNA < 25 IU/mL 12 weeks after the last planned dose of study medication.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements. Known instances of nonconformance were documented and are not considered to have had an impact on the overall conclusions of this study.The study protocol and amendments were reviewed by an Independent Ethics Committee or Institutional Review Board.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 December 2011
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	Austria: 5
Country: Number of subjects enrolled	Belgium: 2
Country: Number of subjects enrolled	Germany: 12
Country: Number of subjects enrolled	Spain: 25
Country: Number of subjects enrolled	France: 7
Country: Number of subjects enrolled	United Kingdom: 10
Country: Number of subjects enrolled	Italy: 13
Worldwide total number of subjects	74
EEA total number of subjects	74

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)	71
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Approximately 72 participants were planned to be included in this study.

Pre-assignment

Screening details:

74 participants received at least one dose of study drugs: 50 participants were on a stable regimen with tacrolimus (TAC) and 24 participants were on a stable regimen with cyclosporine A (CsA).

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	Telaprevir/Peg-IFN-alfa-2a/RBV and Tacrolimus

Arm description:

Subjects received Telaprevir 750 mg q8h in combination with Peg-IFN-alfa-2a, RBV and Tacrolimus. All subjects received Tacrolimus (Immunosuppressive therapy) throughout the study. Prestudy, this immunosuppressant therapy had to be stable, defined as no change in immunosuppressive agents and dose for 1 month prior to the screening visit.

Arm type	Experimental
Investigational medicinal product name	Telaprevir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

750 miligram (mg), administrered as two 375-mg tablets, every 8 hours (q8h) up to Week 12.

Investigational medicinal product name	Pegylated interferon [Peg-IFN-alfa-2a]
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

180 microgram per week [µg/week], up to 48 weeks.

Investigational medicinal product name	Ribavirin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

600 milligram per day [mg/day] (twice daily regimen) as starting dose.

Investigational medicinal product name	Tacrolimus (TAC)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

For subjects whose pre-telaprevir TAC dose was 5 mg or less daily, the starting dose was between 0.2 mg (pediatric formulation) and 0.5 mg of TAC with subsequent dosing every 3 to 5 days.

Arm title	Telaprevir/Peg-IFN-alfa-2a/RBV and Cyclosporine A

Arm description:

Subjects received Telaprevir 750 mg q8h in combination with Peg-IFN-alfa-2a, RBV and cyclosporine A. All subjects received cyclosporine A (Immunosuppressive therapy) throughout the study. Prestudy, this immunosuppressant therapy had to be stable, defined as no change in immunosuppressive agents and dose for 1 month prior to the screening visit.

Arm type	Experimental
Investigational medicinal product name	Telaprevir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

750 miligram (mg), administrered as two 375-mg tablets, every 8 hours (q8h) up to Week 12.

Investigational medicinal product name	Pegylated interferon [Peg-IFN-alfa-2a]
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

180 microgram per week [µg/week], up to 48 weeks.

Investigational medicinal product name	Ribavirin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

600 milligram per day [mg/day] (twice daily regimen) as starting dose.

Investigational medicinal product name	Cyclosporine A
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

For subjects whose pre-telaprevir dose was 100 to 200 mg CsA daily, the starting dose of CsA was between 25 and 50 mg daily.

Number of subjects in period 1	Telaprevir/Peg-IFN-alfa-2a/RBV and Tacrolimus	Telaprevir/Peg-IFN-alfa-2a/RBV and Cyclosporine A
Started	50	24
Completed	43	21
Not completed	7	3
Consent withdrawn by subject	4	3

Lost to follow-up	1	-
Subject ineligible to continue the trial	2	-

Baseline characteristics

Reporting groups	
Reporting group title	Telaprevir/Peg-IFN-alfa-2a/RBV and Tacrolimus
Reporting group description:	
Subjects received Telaprevir 750 mg q8h in combination with Peg-IFN-alfa-2a, RBV and Tacrolimus. All subjects received Tacrolimus (Immunosuppressive therapy) throughout the study. Prestudy, this immunosuppressant therapy had to be stable, defined as no change in immunosuppressive agents and dose for 1 month prior to the screening visit.	
Reporting group title	Telaprevir/Peg-IFN-alfa-2a/RBV and Cyclosporine A
Reporting group description:	
Subjects received Telaprevir 750 mg q8h in combination with Peg-IFN-alfa-2a, RBV and cyclosporine A. All subjects received cyclosporine A (Immunosuppressive therapy) throughout the study. Prestudy, this immunosuppressant therapy had to be stable, defined as no change in immunosuppressive agents and dose for 1 month prior to the screening visit.	

Reporting group values	Telaprevir/Peg-IFN-alfa-2a/RBV and Tacrolimus	Telaprevir/Peg-IFN-alfa-2a/RBV and Cyclosporine A	Total
Number of subjects	50	24	74
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-65 years)	48	23	71
From 66 to 84 years	2	1	3
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	57	54.9	
standard deviation	± 5.25	± 6.33	-
Title for Gender Units: subjects			
Female	3	3	6
Male	47	21	68

End points

End points reporting groups

Reporting group title	Telaprevir/Peg-IFN-alfa-2a/RBV and Tacrolimus

Reporting group description:

Subjects received Telaprevir 750 mg q8h in combination with Peg-IFN-alfa-2a, RBV and Tacrolimus. All subjects received Tacrolimus (Immunosuppressive therapy) throughout the study. Prestudy, this immunosuppressant therapy had to be stable, defined as no change in immunosuppressive agents and dose for 1 month prior to the screening visit.

Reporting group title	Telaprevir/Peg-IFN-alfa-2a/RBV and Cyclosporine A

Reporting group description:

Subjects received Telaprevir 750 mg q8h in combination with Peg-IFN-alfa-2a, RBV and cyclosporine A. All subjects received cyclosporine A (Immunosuppressive therapy) throughout the study. Prestudy, this immunosuppressant therapy had to be stable, defined as no change in immunosuppressive agents and dose for 1 month prior to the screening visit.

Subject analysis set title	All Subjects (Full Analysis (FA) Set)
Subject analysis set type	Full analysis

Subject analysis set description:

FAS included all subjects who received at least one dose of study drugs.

Primary: Percentage of Participants Achieving Sustained Virologic Response (SVR12) (planned [snapshot])

End point title	Percentage of Participants Achieving Sustained Virologic Response (SVR12) (planned [snapshot])[1]

End point description:

SVR12 (planned) is defined as having plasma hepatitis C virus (HCV) ribonucleic acid (RNA) levels less than (<) 25 international unit per milliliter (IU/mL), 12 weeks after the last planned dose of study drugs. Snapshot approach is where the SVR assessment was based on the last HCV RNA value using a lower limit of quantification (LLOQ) of 25 IU/mL in the Week 12 follow-up visit window. The primary analysis on the primary endpoint was conducted using descriptive statistics along with the 95% exact CI for the proportion. The lower bound of the 2-sided 95% CI of SVR12planned in this study (59.9%) excluded the prespecified historical control SVR rate with Peg-IFN/RBV only (31%). Consequently, the null hypothesis that SVR in this study is 31%, is rejected.

End point type	Primary

End point timeframe:

Week 60

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	Telaprevir/Peg-IFN-alfa-2a/RBV and Tacrolimus	Telaprevir/Peg-IFN-alfa-2a/RBV and Cyclosporine A	All Subjects (Full Analysis (FA) Set)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	50[2]	24[3]	74[4]	
Units: percentage of participants				
number (confidence interval 95%)	66 (51.2 to 78.8)	83.3 (62.6 to 95.3)	71.6 (59.9 to 81.5)	

Notes:

[2] - FAS

[3] - FAS

[4] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving sustained virologic response (SVR) 24 planned

End point title	Percentage of Participants Achieving sustained virologic response (SVR) 24 planned

End point description:

SVR24 planned is defined as having plasma HCV RNA levels <25 IU/mL 24 weeks after the last planned dose of study drugs, based on the last plasma HCV RNA value using an LLOQ of 25 IU/mL in the Week 24 follow-up visit window.

End point type	Secondary

End point timeframe:

Week 72

End point values	Telaprevir/Peg-IFN-alfa-2a/RBV and Tacrolimus	Telaprevir/Peg-IFN-alfa-2a/RBV and Cyclosporine A	All Subjects (Full Analysis (FA) Set)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	50[5]	24[6]	74[7]	
Units: Percentage of Participants				
number (not applicable)	68	83.3	73	

Notes:

[5] - FAS

[6] - FAS

[7] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Rapid Virologic Response (RVR)

End point title	Percentage of Participants with Rapid Virologic Response (RVR)

End point description:

RVR defined as having plasma HCV RNA levels '<25 IU/mL, target not detected' at Week 4 of treatment.

End point type	Secondary

End point timeframe:

Week 4

End point values	Telaprevir/Peg-IFN-alfa-2a/RBV and Tacrolimus	Telaprevir/Peg-IFN-alfa-2a/RBV and Cyclosporine A	All Subjects (Full Analysis (FA) Set)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	50[8]	24[9]	74[10]	
Units: Percentage of Participants				
number (not applicable)	38	16.7	31.1	

Notes:

[8] - FAS

[9] - FAS

[10] - FAS

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:

eRVR is defined as having plasma HCV RNA levels <25 IU/mL, 'target not detected' at Week 4 and Week 12 of treatment.

End point type	Secondary

End point timeframe:

Week 4, Week 12

End point values	Telaprevir/Peg-IFN-alfa-2a/RBV and Tacrolimus	Telaprevir/Peg-IFN-alfa-2a/RBV and Cyclosporine A	All Subjects (Full Analysis (FA) Set)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	50[11]	24[12]	74[13]	
Units: Percentage of Participants				
number (not applicable)	38	16.7	31.1	

Notes:

[11] - FAS

[12] - FAS

[13] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Complete Early Virologic Response (cEVR)

End point title	Percentage of Participants with Complete Early Virologic Response (cEVR)

End point description:

cEVR is defined as having plasma HCV RNA levels <25 IU/mL, target not detected at Week 12 of treatment.

End point type	Secondary

End point timeframe:

Week 12

End point values	Telaprevir/Peg-IFN-alfa-2a/RBV and Tacrolimus	Telaprevir/Peg-IFN-alfa-2a/RBV and Cyclosporine A	All Subjects (Full Analysis (FA) Set)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	50[14]	24[15]	74[16]	
Units: Percentage of Participants				
number (not applicable)	80	87.5	82.4	

Notes:

[14] - FAS

[15] - FAS

[16] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Having Plasma HCV RNA levels <25 IU/mL, Target not Detected' at the Actual End of Treatment

End point title	Percentage of Participants Having Plasma HCV RNA levels <25 IU/mL, Target not Detected' at the Actual End of Treatment

End point description:

End point type	Secondary

End point timeframe:

Week 48 or early discontinuation

End point values	Telaprevir/Peg-IFN-alfa-2a/RBV and Tacrolimus	Telaprevir/Peg-IFN-alfa-2a/RBV and Cyclosporine A	All Subjects (Full Analysis (FA) Set)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	50[17]	24[18]	74[19]	
Units: Percentage of Participants				
number (not applicable)	78	83.3	79.7	

Notes:

[17] - FAS

[18] - FAS

[19] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Having Plasma HCV RNA levels <25 IU/mL, Target not Detected, at the Planned End of Treatment

End point title	Percentage of Participants Having Plasma HCV RNA levels <25 IU/mL, Target not Detected, at the Planned End of Treatment

End point description:

End point type	Secondary

End point timeframe:

Week 48

End point values	Telaprevir/Peg-IFN-alfa-2a/RBV and Tacrolimus	Telaprevir/Peg-IFN-alfa-2a/RBV and Cyclosporine A	All Subjects (Full Analysis (FA) Set)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	44[20]	21[21]	65[22]	
Units: Percentage of Participants				
number (not applicable)	79.5	90.5	83.1	

Notes:

[20] - FAS

[21] - FAS

[22] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with On-treatment Virologic Failure

End point title	Percentage of Participants with On-treatment Virologic Failure

End point description:

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

End point type	Secondary

End point timeframe:

Baseline (Week 1) up to Week 48

End point values	Telaprevir/Peg-IFN-alfa-2a/RBV and Tacrolimus	Telaprevir/Peg-IFN-alfa-2a/RBV and Cyclosporine A	All Subjects (Full Analysis (FA) Set)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	50[23]	24[24]	74[25]	
Units: Percentage of Participants				
number (not applicable)	12	8.3	10.8	

Notes:

[23] - FAS

[24] - FAS

[25] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Relapse (Snapshot)

End point title	Percentage of Participants with Relapse (Snapshot)

End point description:

Relapse (Snapshot), defined as having confirmed detectable plasma HCV RNA (greater than or equal to (>=) 25 IU/mL) from planned end of treatment (ie, Week 48) onwards after previous `<25 IU/mL at planned end of treatment, and not achieving SVR12planned (Snapshot).
Number of subjects analyzed included subjects who had HCV RNA <25 IU/mL at planned end of treatment, or a missing HCV RNA assessment at planned end of treatment (EOT) and HCV RNA <25 IU/mL during follow-up from planned EOT onwards.

End point type	Secondary

End point timeframe:

Week 48 up to Week 60

End point values	Telaprevir/Peg-IFN-alfa-2a/RBV and Tacrolimus	Telaprevir/Peg-IFN-alfa-2a/RBV and Cyclosporine A	All Subjects (Full Analysis (FA) Set)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	37[26]	19[27]	56[28]	
Units: Percentage of Participants				
number (not applicable)	10.8	0	7.1	

Notes:

[26] - FAS

[27] - FAS

[28] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Viral Breakthrough

End point title	Percentage of Participants with Viral Breakthrough

End point description:

Viral breakthrough, defined as an increase >1 log10 in plasma HCV RNA level from the lowest level reached, or a value of HCV RNA >100 IU/mL in subjects whose HCV RNA had previously became <25 IU/mL during treatment.

End point type	Secondary

End point timeframe:

Baseline (Week 1) up to Week 48

End point values	Telaprevir/Peg-IFN-alfa-2a/RBV and Tacrolimus	Telaprevir/Peg-IFN-alfa-2a/RBV and Cyclosporine A	All Subjects (Full Analysis (FA) Set)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	50[29]	24[30]	74[31]	
Units: Percentage of Participants				
number (not applicable)	10	8.3	9.5	

Notes:
[29] - FAS
[30] - FAS
[31] - FAS

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Timeframe for AE	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	14.1

Reporting groups	
Reporting group title	Telaprevir/Peg-IFN-alfa-2a/RBV and cyclosporine A
Reporting group description:	
Subjects received Telaprevir 750 mg q8h in combination with Peg-IFN-alfa-2a, RBV and cyclosporine A.	
Reporting group title	Telaprevir/Peg-IFN-alfa-2a/RBV and Tacrolimus
Reporting group description:	
Subjects received Telaprevir 750 mg q8h in combination with Peg-IFN-alfa-2a, RBV and tacrolimus.	

Serious adverse events	Telaprevir/Peg-IFN-alfa-2a/RBV and cyclosporine A	Telaprevir/Peg-IFN-alfa-2a/RBV and Tacrolimus	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 24 (8.33%)	7 / 50 (14.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General Physical Health Deterioration			

subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Lens Dislocation			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Ascites			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Autoimmune Hepatitis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholestasis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Renal Failure Acute			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Urinary Tract Infection			

subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Telaprevir/Peg-IFN-alfa-2a/RBV and cyclosporine A	Telaprevir/Peg-IFN-alfa-2a/RBV and Tacrolimus	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 24 (100.00%)	50 / 50 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cholesteatoma			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Hot Flush			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Hypertension			
subjects affected / exposed	1 / 24 (4.17%)	1 / 50 (2.00%)	
occurrences (all)	1	1	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	11 / 24 (45.83%)	15 / 50 (30.00%)	
occurrences (all)	19	19	
Fatigue			
subjects affected / exposed	5 / 24 (20.83%)	16 / 50 (32.00%)	
occurrences (all)	5	22	
Chills			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Feeling Cold			

subjects affected / exposed	2 / 24 (8.33%)	0 / 50 (0.00%)	
occurrences (all)	2	0	
Feeling Hot			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Influenza Like Illness			
subjects affected / exposed	1 / 24 (4.17%)	2 / 50 (4.00%)	
occurrences (all)	1	3	
Irritability			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Injection Site Erythema			
subjects affected / exposed	0 / 24 (0.00%)	2 / 50 (4.00%)	
occurrences (all)	0	4	
Mucosal Dryness			
subjects affected / exposed	1 / 24 (4.17%)	1 / 50 (2.00%)	
occurrences (all)	1	2	
Malaise			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Mucosal Inflammation			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Oedema Peripheral			
subjects affected / exposed	0 / 24 (0.00%)	3 / 50 (6.00%)	
occurrences (all)	0	3	
Pyrexia			
subjects affected / exposed	5 / 24 (20.83%)	10 / 50 (20.00%)	
occurrences (all)	10	13	
Reproductive system and breast disorders			
Erectile Dysfunction			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Penile Blister			

subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Prostatitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 24 (16.67%)	5 / 50 (10.00%)	
occurrences (all)	4	5	
Asthma			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Dyspnoea			
subjects affected / exposed	4 / 24 (16.67%)	8 / 50 (16.00%)	
occurrences (all)	4	8	
Dyspnoea Exertional			
subjects affected / exposed	0 / 24 (0.00%)	3 / 50 (6.00%)	
occurrences (all)	0	3	
Nasal Congestion			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Oropharyngeal Pain			
subjects affected / exposed	0 / 24 (0.00%)	2 / 50 (4.00%)	
occurrences (all)	0	3	
Pleural Effusion			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Psychiatric disorders			
Affect Lability			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Anxiety			
subjects affected / exposed	0 / 24 (0.00%)	2 / 50 (4.00%)	
occurrences (all)	0	2	
Depressed Mood			

subjects affected / exposed	0 / 24 (0.00%)	2 / 50 (4.00%)	
occurrences (all)	0	2	
Depression			
subjects affected / exposed	1 / 24 (4.17%)	3 / 50 (6.00%)	
occurrences (all)	1	3	
Insomnia			
subjects affected / exposed	4 / 24 (16.67%)	6 / 50 (12.00%)	
occurrences (all)	4	6	
Mood Swings			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Nervousness			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 24 (0.00%)	2 / 50 (4.00%)	
occurrences (all)	0	2	
Blood Bilirubin Increased			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Blood Amylase Increased			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Blood Creatinine Increased			
subjects affected / exposed	0 / 24 (0.00%)	2 / 50 (4.00%)	
occurrences (all)	0	2	
Blood Glucose Increased			
subjects affected / exposed	0 / 24 (0.00%)	2 / 50 (4.00%)	
occurrences (all)	0	2	
Blood Magnesium Decreased			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Blood Uric Acid Increased			
subjects affected / exposed	1 / 24 (4.17%)	7 / 50 (14.00%)	
occurrences (all)	2	15	

Blood Phosphorus Decreased			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Body Temperature Increased			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Blood Urine Present			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Electrocardiogram QT Prolonged			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Electrocardiogram T Wave Inversion			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Haemoglobin Decreased			
subjects affected / exposed	1 / 24 (4.17%)	1 / 50 (2.00%)	
occurrences (all)	1	1	
Gamma-Glutamyltransferase Increased			
subjects affected / exposed	1 / 24 (4.17%)	1 / 50 (2.00%)	
occurrences (all)	1	1	
Mean Cell Volume Increased			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Platelet Count Decreased			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Weight Decreased			
subjects affected / exposed	1 / 24 (4.17%)	2 / 50 (4.00%)	
occurrences (all)	1	3	
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			

Excoriation			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Incisional Hernia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Limb Injury			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Scratch			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Skin Injury			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Sunburn			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Cardiac disorders			
Sinus Tachycardia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Rebound Tachycardia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Tachycardia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Disturbance in Attention			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Burning Sensation			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Dizziness			

subjects affected / exposed	1 / 24 (4.17%)	4 / 50 (8.00%)	
occurrences (all)	1	5	
Dysgeusia			
subjects affected / exposed	0 / 24 (0.00%)	3 / 50 (6.00%)	
occurrences (all)	0	3	
Headache			
subjects affected / exposed	8 / 24 (33.33%)	17 / 50 (34.00%)	
occurrences (all)	12	21	
Lethargy			
subjects affected / exposed	0 / 24 (0.00%)	2 / 50 (4.00%)	
occurrences (all)	0	2	
Neuropathy Peripheral			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Migraine			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Restless Legs Syndrome			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Syncope			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Tremor			
subjects affected / exposed	1 / 24 (4.17%)	1 / 50 (2.00%)	
occurrences (all)	1	1	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	13 / 24 (54.17%)	24 / 50 (48.00%)	
occurrences (all)	27	38	
Lymphopenia			
subjects affected / exposed	0 / 24 (0.00%)	2 / 50 (4.00%)	
occurrences (all)	0	3	
Leukopenia			
subjects affected / exposed	3 / 24 (12.50%)	7 / 50 (14.00%)	
occurrences (all)	4	12	

Pancytopenia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Neutropenia			
subjects affected / exposed	4 / 24 (16.67%)	8 / 50 (16.00%)	
occurrences (all)	4	11	
Thrombocytopenia			
subjects affected / exposed	4 / 24 (16.67%)	14 / 50 (28.00%)	
occurrences (all)	6	22	
Ear and labyrinth disorders			
Ear Discomfort			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	2	
Ear Pruritus			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	2	0	
Vertigo			
subjects affected / exposed	2 / 24 (8.33%)	0 / 50 (0.00%)	
occurrences (all)	2	0	
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 24 (0.00%)	2 / 50 (4.00%)	
occurrences (all)	0	2	
Vision Blurred			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Dry Eye			
subjects affected / exposed	0 / 24 (0.00%)	2 / 50 (4.00%)	
occurrences (all)	0	2	
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	1 / 24 (4.17%)	2 / 50 (4.00%)	
occurrences (all)	1	2	
Abdominal Distension			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Abdominal Pain Upper			

subjects affected / exposed	0 / 24 (0.00%)	2 / 50 (4.00%)	
occurrences (all)	0	2	
Abdominal Pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	2	
Anal Pruritus			
subjects affected / exposed	5 / 24 (20.83%)	9 / 50 (18.00%)	
occurrences (all)	7	9	
Anorectal Discomfort			
subjects affected / exposed	3 / 24 (12.50%)	6 / 50 (12.00%)	
occurrences (all)	3	7	
Aphthous Stomatitis			
subjects affected / exposed	2 / 24 (8.33%)	1 / 50 (2.00%)	
occurrences (all)	2	1	
Ascites			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Breath Odour			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Chapped Lips			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Cheilitis			
subjects affected / exposed	2 / 24 (8.33%)	0 / 50 (0.00%)	
occurrences (all)	2	0	
Constipation			
subjects affected / exposed	2 / 24 (8.33%)	1 / 50 (2.00%)	
occurrences (all)	2	1	
Diarrhoea			
subjects affected / exposed	2 / 24 (8.33%)	17 / 50 (34.00%)	
occurrences (all)	2	19	
Dry Mouth			
subjects affected / exposed	1 / 24 (4.17%)	2 / 50 (4.00%)	
occurrences (all)	1	2	
Dyspepsia			

subjects affected / exposed	4 / 24 (16.67%)	2 / 50 (4.00%)	
occurrences (all)	4	2	
Gastrooesophageal Reflux Disease			
subjects affected / exposed	1 / 24 (4.17%)	1 / 50 (2.00%)	
occurrences (all)	1	1	
Gingival Pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Glossodynia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Haemorrhoids			
subjects affected / exposed	2 / 24 (8.33%)	8 / 50 (16.00%)	
occurrences (all)	2	8	
Haematochezia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Hyperchlorhydria			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Nausea			
subjects affected / exposed	6 / 24 (25.00%)	11 / 50 (22.00%)	
occurrences (all)	8	15	
Painful Defaecation			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Proctalgia			
subjects affected / exposed	0 / 24 (0.00%)	5 / 50 (10.00%)	
occurrences (all)	0	5	
Rectal Haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Swollen Tongue			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Stomatitis			

subjects affected / exposed	0 / 24 (0.00%)	2 / 50 (4.00%)	
occurrences (all)	0	2	
Tongue Ulceration			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Toothache			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Vomiting			
subjects affected / exposed	2 / 24 (8.33%)	6 / 50 (12.00%)	
occurrences (all)	3	7	
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	2	
Jaundice			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 24 (0.00%)	2 / 50 (4.00%)	
occurrences (all)	0	2	
Dermatitis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Dry Skin			
subjects affected / exposed	2 / 24 (8.33%)	5 / 50 (10.00%)	
occurrences (all)	2	6	
Eczema			
subjects affected / exposed	0 / 24 (0.00%)	2 / 50 (4.00%)	
occurrences (all)	0	2	
Erythema			
subjects affected / exposed	1 / 24 (4.17%)	2 / 50 (4.00%)	
occurrences (all)	1	4	
Lichenification			

subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Night Sweats			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Petechiae			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Pruritus			
subjects affected / exposed	6 / 24 (25.00%)	27 / 50 (54.00%)	
occurrences (all)	8	31	
Pruritus Generalised			
subjects affected / exposed	0 / 24 (0.00%)	2 / 50 (4.00%)	
occurrences (all)	0	2	
Rash			
subjects affected / exposed	3 / 24 (12.50%)	17 / 50 (34.00%)	
occurrences (all)	3	21	
Rash Erythematous			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Rash Maculo-Papular			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	2	
Skin Ulcer			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Rash Papular			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Swelling Face			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Renal and urinary disorders			
Azotaemia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	

Incontinence			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Dysuria			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Nocturia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Renal Failure			
subjects affected / exposed	1 / 24 (4.17%)	1 / 50 (2.00%)	
occurrences (all)	1	1	
Renal Impairment			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	2 / 24 (8.33%)	1 / 50 (2.00%)	
occurrences (all)	2	1	
Arthralgia			
subjects affected / exposed	3 / 24 (12.50%)	6 / 50 (12.00%)	
occurrences (all)	3	7	
Muscle Spasms			
subjects affected / exposed	1 / 24 (4.17%)	5 / 50 (10.00%)	
occurrences (all)	1	5	
Pain in Extremity			
subjects affected / exposed	0 / 24 (0.00%)	3 / 50 (6.00%)	
occurrences (all)	0	3	
Myalgia			
subjects affected / exposed	2 / 24 (8.33%)	6 / 50 (12.00%)	
occurrences (all)	3	6	
Infections and infestations			
Anal Abscess			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Bronchitis			

subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Dermatitis Infected			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Bronchopneumonia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Ear Infection			
subjects affected / exposed	1 / 24 (4.17%)	1 / 50 (2.00%)	
occurrences (all)	1	1	
Enterobiasis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	2	0	
Escherichia Sepsis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Gastroenteritis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 24 (0.00%)	2 / 50 (4.00%)	
occurrences (all)	0	2	
Influenza			
subjects affected / exposed	3 / 24 (12.50%)	6 / 50 (12.00%)	
occurrences (all)	3	6	
Oral Candidiasis			
subjects affected / exposed	0 / 24 (0.00%)	3 / 50 (6.00%)	
occurrences (all)	0	3	
Nasopharyngitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Urinary Tract Infection			
subjects affected / exposed	1 / 24 (4.17%)	2 / 50 (4.00%)	
occurrences (all)	1	2	
Metabolism and nutrition disorders			

Cachexia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Decreased Appetite			
subjects affected / exposed	1 / 24 (4.17%)	9 / 50 (18.00%)	
occurrences (all)	1	9	
Hypercholesterolaemia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Hypercreatininaemia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Hyperglycaemia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Hyperkalaemia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Hypertriglyceridaemia			
subjects affected / exposed	1 / 24 (4.17%)	2 / 50 (4.00%)	
occurrences (all)	1	3	
Hyperuricaemia			
subjects affected / exposed	6 / 24 (25.00%)	3 / 50 (6.00%)	
occurrences (all)	10	4	
Hypoglycaemia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Hypomagnesaemia			
subjects affected / exposed	0 / 24 (0.00%)	2 / 50 (4.00%)	
occurrences (all)	0	3	
Impaired Fasting Glucose			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Metabolic Disorder			
subjects affected / exposed	0 / 24 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
31 May 2012	The primary analysis was changed to a snapshot analysis. SVR12 planned and SVR24 planned were analyzed using a snapshot approach, where the SVR assessment is based on the last HCV RNA value utilizing lower limit of quantification (LLOQ; 25 IU/mL) in the Week 12 and Week 24 follow-up visit window, respectively. The snapshot analysis has been accepted by the European Medicines Agency and Food and Drug Administration for previous telaprevir Phase 3 studies.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported