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Trial record **1 of 1** for: CR013711

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VX-950-C211 - A Dosing Regimen Study (Twice Daily Versus Every 8 Hours) of Telaprevir in Treatment-naïve Participants With Genotype 1 Chronic Hepatitis C Virus Infection

This study has been completed.

Sponsor:
Janssen Infectious Diseases BVBA

Collaborator:
Vertex Pharmaceuticals Incorporated

Information provided by (Responsible Party):
Janssen Infectious Diseases BVBA

ClinicalTrials.gov Identifier:
NCT01241760

First received: October 28, 2010
Last updated: May 14, 2014
Last verified: May 2014
History of Changes

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Results First Received: September 23, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Genotype 1 Chronic Hepatitis C Treatment Naive
Interventions:	Drug: Ribavirin Drug: Telaprevir Drug: Pegylated interferon alfa-2a

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
This study evaluated the effectiveness of telaprevir administered twice daily versus every 8 hours in combination with pegylated interferon and ribavirin in treatment-naïve participants with chronic HCV genotype 1 infection.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
The study was conducted between 15 November 2010 and 02 August 2012 and recruited participants from 125 study centers in 14 countries worldwide. 744 participants were initially enrolled and 740 out of them randomly allocated to the 2 treatment arms.

Reporting Groups

	Description
T12(q8h)/PR	Telaprevir 750 mg (2 oral tablets) every 8 hours for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.
T12(b.i.d.)/PR	Telaprevir 1125 mg (3 oral tablets) twice a day (every 10-14 hours) for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.

Participant Flow: Overall Study

	T12(q8h)/PR	T12(b.i.d.)/PR
STARTED	**371**	**369**

COMPLETED	337	329
NOT COMPLETED	34	40
Adverse Event	1	0
Lost to Follow-up	18	22
Withdrawal by Subject	13	13
Switch To Commercially Available Medicat	1	4
Not specified	1	1

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
T12(q8h)/PR	Telaprevir 750 mg (2 oral tablets) every 8 hours for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.
T12(b.i.d.)/PR	Telaprevir 1125 mg (3 oral tablets) twice a day (every 10-14 hours) for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.
Total	Total of all reporting groups

Baseline Measures

	T12(q8h)/PR	T12(b.i.d.)/PR	Total
Number of Participants [units: participants]	371	369	740
Age [units: participants]			
<=18 years	3	0	3
Between 18 and 65 years	351	362	713
>=65 years	17	7	24
Age [units: years] Mean (Full Range)	48 (18 to 70)	47.5 (19 to 70)	47.7 (18 to 70)
Gender [units: participants]			
Female	136	160	296
Male	235	209	444
Region of Enrollment [units: participants]			
Europe	192	179	371
North-America	126	137	263
Australia	28	28	56
Mexico	5	4	9
Brazil	20	21	41

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants With Sustained Virologic Response (SVR) 12 Weeks After the Last Planned Dose of Study Drugs (SVR12 Planned) [Time Frame: End of trial, 12 weeks after last planned dose]

Measure Type	Primary
Measure Title	Percentage of Participants With Sustained Virologic Response (SVR) 12 Weeks After the Last Planned Dose of Study Drugs (SVR12 Planned)
Measure Description	The table below shows the percentage of participants achieving Sustained Virologic Response 12 weeks after last planned dose of study medication (SVR12 planned). SVR was defined as having Hepatitis C Virus (HCV) ribonucleic acid (RNA) levels less than 25 international units/milliliter (IU/mL).
Time Frame	End of trial, 12 weeks after last planned dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All analyses were performed on the full analysis (FA) set, which was defined as all randomized subjects who received at least one dose of study drug.

Reporting Groups

	Description
T12(q8h)/PR	Telaprevir 750 mg (2 oral tablets) every 8 hours for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.
T12(b.i.d.)/PR	Telaprevir 1125 mg (3 oral tablets) twice a day (every 10-14 hours) for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.

Measured Values

	T12 (q8h)/PR	**T12 (b.i.d.)/PR**
Number of Participants Analyzed [units: participants]	**371**	**369**
Percentage of Participants With Sustained Virologic Response (SVR) 12 Weeks After the Last Planned Dose of Study Drugs (SVR12 Planned) [units: percentage of participants with response]	**72.8**	**74.3**

Statistical Analysis 1 for Percentage of Participants With Sustained Virologic Response (SVR) 12 Weeks After the Last Planned Dose of Study Drugs (SVR12 Planned)

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	Regression, Logistic
Difference in proportion of response, % [4]	1.5
95% Confidence Interval	-4.9 to 12

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	If the lower limit of the 95% confidence interval of the difference in proportions was above the pre-determined non-inferiority margin of -11%, non-inferiority was established.
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	The 95% confidence interval of the difference in proportions was estimated using a logistic regression model.
[4]	Other relevant estimation information:

	Observed data

2. Secondary: Percentage of Participants With Sustained Virologic Response 24 Weeks After the Last Planned Dose of Study Drugs (SVR24 Planned) [Time Frame: End of trial, 24 weeks after last planned dose]

Measure Type	Secondary
Measure Title	Percentage of Participants With Sustained Virologic Response 24 Weeks After the Last Planned Dose of Study Drugs (SVR24 Planned)
Measure Description	The table below shows the percentage of participants achieving SVR 24 weeks after the last planned dose of study medication. SVR was defined as having Hepatitis C Virus (HCV) ribonucleic acid (RNA) levels less than 25 international units/milliliter (IU/mL). The response for T12(b.i.d)/PR group is higher than that after 12 weeks because HCV RNA data for two participants were missing for SVR assessment at that time. Consequently, by definition of SVR12, they were counted as not having achieved SVR12.
Time Frame	End of trial, 24 weeks after last planned dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All analyses were performed on the full analysis (FA) set, which was defined as all randomized subjects who received at least one dose of study drug.

Reporting Groups

	Description
T12(q8h)/PR	Telaprevir 750 mg (2 oral tablets) every 8 hours for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.
T12(b.i.d.)/PR	Telaprevir 1125 mg (3 oral tablets) twice a day (every 10-14 hours) for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.

Measured Values

	T12 (q8h)/PR	**T12 (b.i.d.)/PR**
Number of Participants Analyzed [units: participants]	**371**	**369**
Percentage of Participants With Sustained Virologic Response 24 Weeks After the Last Planned Dose of Study Drugs (SVR24 Planned) [units: percentage of participants with response]	**72.8**	**74.8**

No statistical analysis provided for Percentage of Participants With Sustained Virologic Response 24 Weeks After the Last Planned Dose of Study Drugs (SVR24 Planned)

3. Secondary: Percentage of Participants With Sustained Virologic Response 72 Weeks After the Start of Study Medication (SVR72 Planned) [Time Frame: End of trial, 72 weeks after the start of study medication]

Measure Type	Secondary
Measure Title	Percentage of Participants With Sustained Virologic Response 72 Weeks After the Start of Study Medication (SVR72 Planned)
Measure Description	The table below shows the percentage of participants achieving SVR 72 weeks after the start of study medication (SVR72 planned). SVR was defined as having plasma Hepatitis C Virus (HCV) ribonucleic acid (RNA) levels less than 25 IU/mL, target not detected, at end of treatment and up to 72 weeks after start of study medication (i.e., no confirmed detectable HCV RNA in between).
Time Frame	End of trial, 72 weeks after the start of study medication
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All analyses were performed on the full analysis (FA) set, which was defined as all randomized subjects who received at least one dose of study drug.

Reporting Groups

	Description
T12(q8h)/PR	Telaprevir 750 mg (2 oral tablets) every 8 hours for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.
T12(b.i.d.)/PR	Telaprevir 1125 mg (3 oral tablets) twice a day (every 10-14 hours) for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.

Measured Values

	T12 (q8h)/PR	**T12 (b.i.d.)/PR**
Number of Participants Analyzed [units: participants]	**371**	**369**
Percentage of Participants With Sustained Virologic Response 72 Weeks After the Start of Study Medication (SVR72 Planned) [units: percentage of participants with response]	**69.0**	**70.2**

No statistical analysis provided for Percentage of Participants With Sustained Virologic Response 72 Weeks After the Start of Study Medication (SVR72 Planned)

4. Secondary: Percentage of Participants Achieving Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Values of Less Than 25 IU/ml, Target Not Detected, at Different Time Points. [Time Frame: Baseline, Week 4 and Week 4+12.]

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Values of Less Than 25 IU/ml, Target Not Detected, at Different Time Points.
Measure Description	The table below shows the percentage of participants with undetectable hepatitis C virus (HCV) ribonucleic acid (RNA) levels, which means less than 25 IU/ml, target not detected, at different time points during the study.
Time Frame	Baseline, Week 4 and Week 4+12.
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All analyses were performed on the full analysis (FA) set, which was defined as all randomized subjects who received at least one dose of study drug.

Reporting Groups

	Description
T12(q8h)/PR	Telaprevir 750 mg (2 oral tablets) every 8 hours for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.
T12(b.i.d.)/PR	Telaprevir 1125 mg (3 oral tablets) twice a day (every 10-14 hours) for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.

Measured Values

	T12 (q8h)/PR	**T12 (b.i.d.)/PR**

Number of Participants Analyzed [units: participants]	**371**	**369**
Percentage of Participants Achieving Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Values of Less Than 25 IU/ml, Target Not Detected, at Different Time Points. [units: percentage of participants with response]		
Baseline	**0**	**0**
at Week 4	**67.4**	**69.4**
at Week 4 and Week 12	**63.1**	**66.1**

No statistical analysis provided for Percentage of Participants Achieving Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Values of Less Than 25 IU/ml, Target Not Detected, at Different Time Points.

5. Secondary: Percentage of Participants With On-treatment Virologic Failure Which Required Them to Permanently Discontinue All Study Drugs [Time Frame: Week 4, 12, 24, 32, 40]

Measure Type	Secondary
Measure Title	Percentage of Participants With On-treatment Virologic Failure Which Required Them to Permanently Discontinue All Study Drugs
Measure Description	The table below shows the percentage of participants who met a stopping rule, defined as having a hepatitis C virus (HCV) ribonucleic acid (RNA) value at Week 4 >1000 IU/mL and at Weeks 12, 24, 32 and 40 ≥25 IU/mL.
Time Frame	Week 4, 12, 24, 32, 40
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All analyses were performed on the full analysis (FA) set, which was defined as all randomized subjects who received at least one dose of study drug.

Reporting Groups

	Description
T12(q8h)/PR	Telaprevir 750 mg (2 oral tablets) every 8 hours for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.
T12(b.i.d.)/PR	Telaprevir 1125 mg (3 oral tablets) twice a day (every 10-14 hours) for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.

Measured Values

	T12 (q8h)/PR	**T12 (b.i.d.)/PR**
Number of Participants Analyzed [units: participants]	**371**	**369**
Percentage of Participants With On-treatment Virologic Failure Which Required Them to Permanently Discontinue All Study Drugs [units: percentage of participants]	**9.7**	**10.3**

No statistical analysis provided for Percentage of Participants With On-treatment Virologic Failure Which Required Them to Permanently Discontinue All Study Drugs

6. Secondary: Percentage of Participants Who Relapsed During Follow-up Period [Time Frame: During Follow-Up (24 weeks after the last dose of study drug)]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Relapsed During Follow-up Period

Measure Description	The table below shows the percentage of participants who relapsed (ie, those having confirmed detectable hepatitis C virus [HCV] ribonucleic acid [RNA] during the 12-week follow-up period after previous HCV RNA <25 IU/mL, target not detected, at end of treatment).
Time Frame	During Follow-Up (24 weeks after the last dose of study drug)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The analysis was performed on subjects with HCV RNA <25 IU/mL at the planned end of treatment, which included all randomized participants who received at least one dose of study drug and had data at the follow-up visit performed 24 weeks after the last dose of study drug.

Reporting Groups

	Description
T12(q8h)/PR	Telaprevir 750 mg (2 oral tablets) every 8 hours for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.
T12(b.i.d.)/PR	Telaprevir 1125 mg (3 oral tablets) twice a day (every 10-14 hours) for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.

Measured Values

	T12(q8h)/PR	T12(b.i.d.)/PR
Number of Participants Analyzed [units: participants]	**293**	**300**
Percentage of Participants Who Relapsed During Follow-up Period [units: percentage of participants]	**7.2**	**7.7**

No statistical analysis provided for Percentage of Participants Who Relapsed During Follow-up Period

7. Secondary: Percentage of Participants of Each IL28B Genotype Achieving Sustained Virologic Response 12 Weeks After the Last Planned Dose of Study Medication (SVR12 Planned) [Time Frame: End of trial, 12 weeks after the last planned dose]

Measure Type	Secondary
Measure Title	Percentage of Participants of Each IL28B Genotype Achieving Sustained Virologic Response 12 Weeks After the Last Planned Dose of Study Medication (SVR12 Planned)
Measure Description	The table below shows the effect of interleukin 28B (IL28B) gene's subtype (CC, CT or TT genotype) on the primary outcome measure: SVR12 planned.
Time Frame	End of trial, 12 weeks after the last planned dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All analyses were performed on the full analysis (FA) set, which was defined as all randomized subjects who received at least one dose of study drug.

Reporting Groups

	Description
T12(q8h)/PR	Telaprevir 750 mg (2 oral tablets) every 8 hours for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.
T12(b.i.d.)/PR	Telaprevir 1125 mg (3 oral tablets) twice a day (every 10-14 hours) for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.

Measured Values

	T12 (q8h)/PR	T12 (b.i.d.)/PR
Number of Participants Analyzed [units: participants]	**371**	**369**
Percentage of Participants of Each IL28B Genotype Achieving Sustained Virologic Response 12 Weeks After the Last Planned Dose of Study Medication (SVR12 Planned) [units: percentage of participants with response]		
CC genotype (n = 108; n = 103)	**86.8**	**92.4**
CT genotype (n = 207; n = 207)	**67.8**	**67.5**
TT genotype (n = 56; n = 59)	**64.9**	**65.5**

No statistical analysis provided for Percentage of Participants of Each IL28B Genotype Achieving Sustained Virologic Response 12 Weeks After the Last Planned Dose of Study Medication (SVR12 Planned)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse event data were collected for the duration of study (12 weeks after the last dose).
Additional Description	The total number of adverse events listed in the "Other (non-Serious) Adverse Events" table are based upon a cut-off of greater than or equal to 5 percent of patients experiencing the adverse event in any treatment arm.

Reporting Groups

	Description
T12(q8h)/PR	Telaprevir 750 mg (2 oral tablets) every 8 hours for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.
T12(b.i.d.)/PR	Telaprevir 1125 mg (3 oral tablets) twice a day (every 10-14 hours) for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.
Total	All

Serious Adverse Events

	T12(q8h)/PR	T12(b.i.d.)/PR	Total
Total, serious adverse events			
# participants affected / at risk	**35/371 (9.43%)**	**28/369 (7.59%)**	**63/740 (8.51%)**
Blood and lymphatic system disorders			
Anaemia *1			
# participants affected / at risk	**14/371 (3.77%)**	**13/369 (3.52%)**	**27/740 (3.65%)**
Thrombocytopenia *1			
# participants affected / at risk	**2/371 (0.54%)**	**0/369 (0.00%)**	**2/740 (0.27%)**
Leukopenia *1			
# participants affected / at risk	**1/371 (0.27%)**	**0/369 (0.00%)**	**1/740 (0.14%)**
Neutropenia *1			
# participants affected / at risk	**1/371 (0.27%)**	**0/369 (0.00%)**	**1/740 (0.14%)**
Pancytopenia *1			
# participants affected / at risk	**1/371 (0.27%)**	**1/369 (0.27%)**	**2/740 (0.27%)**
Ear and labyrinth disorders			
Vertigo *1			
# participants affected / at risk	**0/371 (0.00%)**	**2/369 (0.54%)**	**2/740 (0.27%)**
Gastrointestinal disorders			
Diarrhoea *1			
# participants affected / at risk	**1/371 (0.27%)**	**1/369 (0.27%)**	**2/740 (0.27%)**

Haematochezia *1			
# participants affected / at risk	0/371 (0.00%)	1/369 (0.27%)	1/740 (0.14%)
General disorders			
Asthenia *1			
# participants affected / at risk	1/371 (0.27%)	1/369 (0.27%)	2/740 (0.27%)
Chest discomfort *1			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)
Chest pain *1			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)
Fatigue *1			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)
Pyrexia *1			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)
Non-cardiac chest pain *1			
# participants affected / at risk	0/371 (0.00%)	1/369 (0.27%)	1/740 (0.14%)
Hepatobiliary disorders			
Hyperbilirubinaemia *1			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)
Cholelithiasis *1			
# participants affected / at risk	0/371 (0.00%)	1/369 (0.27%)	1/740 (0.14%)
Infections and infestations			
Abscess *1			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)
Cellulitis *1			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)
Escherichia sepsis *1			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)
Sinusitis *1			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)
Subcutaneous abscess *1			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)
Urinary tract infection *1			
# participants affected / at risk	1/371 (0.27%)	1/369 (0.27%)	2/740 (0.27%)
Pneumonia *1			
# participants affected / at risk	0/371 (0.00%)	1/369 (0.27%)	1/740 (0.14%)
Injury, poisoning and procedural complications			
Contusion *1			
# participants affected / at risk	0/371 (0.00%)	1/369 (0.27%)	1/740 (0.14%)
Foot fracture *1			
# participants affected / at risk	0/371 (0.00%)	1/369 (0.27%)	1/740 (0.14%)
Investigations			
Electrocardiogram t wave inversion *1			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)
Metabolism and nutrition disorders			
Dehydration *1			
# participants affected / at risk	2/371 (0.54%)	0/369 (0.00%)	2/740 (0.27%)
Hypokalaemia *1			
# participants affected / at risk	0/371 (0.00%)	1/369 (0.27%)	1/740 (0.14%)
Musculoskeletal and connective tissue disorders			

Intervertebral disc protrusion [*1]			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm [*1]			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)
Uterine leiomyoma [*1]			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)
Nervous system disorders			
Syncope [*1]			
# participants affected / at risk	3/371 (0.81%)	2/369 (0.54%)	5/740 (0.68%)
Facial palsy [*1]			
# participants affected / at risk	0/371 (0.00%)	1/369 (0.27%)	1/740 (0.14%)
Hemiparesis [*1]			
# participants affected / at risk	0/371 (0.00%)	1/369 (0.27%)	1/740 (0.14%)
Hypoaesthesia [*1]			
# participants affected / at risk	0/371 (0.00%)	1/369 (0.27%)	1/740 (0.14%)
Myoclonus [*1]			
# participants affected / at risk	0/371 (0.00%)	1/369 (0.27%)	1/740 (0.14%)
Paraesthesia [*1]			
# participants affected / at risk	0/371 (0.00%)	1/369 (0.27%)	1/740 (0.14%)
Psychiatric disorders			
Depression [*1]			
# participants affected / at risk	1/371 (0.27%)	1/369 (0.27%)	2/740 (0.27%)
Suicide attempt [*1]			
# participants affected / at risk	1/371 (0.27%)	1/369 (0.27%)	2/740 (0.27%)
Disorientation [*1]			
# participants affected / at risk	0/371 (0.00%)	1/369 (0.27%)	1/740 (0.14%)
Mental status changes [*1]			
# participants affected / at risk	0/371 (0.00%)	1/369 (0.27%)	1/740 (0.14%)
Renal and urinary disorders			
Renal failure acute [*1]			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)
Reproductive system and breast disorders			
Menorrhagia [*1]			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)
Postmenopausal haemorrhage [*1]			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)
Vaginal haemorrhage [*1]			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)
Respiratory, thoracic and mediastinal disorders			
Pulmonary hypertension [*1]			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)
Dyspnoea [*1]			
# participants affected / at risk	0/371 (0.00%)	1/369 (0.27%)	1/740 (0.14%)
Pleural effusion [*1]			
# participants affected / at risk	0/371 (0.00%)	1/369 (0.27%)	1/740 (0.14%)
Skin and subcutaneous tissue disorders			
Drug eruption [*1]			
# participants affected / at risk	1/371 (0.27%)	0/369 (0.00%)	1/740 (0.14%)

Rash * 1			
# participants affected / at risk	**1/371 (0.27%)**	**2/369 (0.54%)**	**3/740 (0.41%)**
Rash generalised * 1			
# participants affected / at risk	**1/371 (0.27%)**	**0/369 (0.00%)**	**1/740 (0.14%)**
Urticaria * 1			
# participants affected / at risk	**1/371 (0.27%)**	**0/369 (0.00%)**	**1/740 (0.14%)**
Drug rash with eosinophilia and systemic symptoms * 1			
# participants affected / at risk	**0/371 (0.00%)**	**1/369 (0.27%)**	**1/740 (0.14%)**
Pruritus * 1			
# participants affected / at risk	**0/371 (0.00%)**	**1/369 (0.27%)**	**1/740 (0.14%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 11.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse event data were collected for the duration of study (12 weeks after the last dose).
Additional Description	The total number of adverse events listed in the "Other (non-Serious) Adverse Events" table are based upon a cut-off of greater than or equal to 5 percent of patients experiencing the adverse event in any treatment arm.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
T12(q8h)/PR	Telaprevir 750 mg (2 oral tablets) every 8 hours for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.
T12(b.i.d.)/PR	Telaprevir 1125 mg (3 oral tablets) twice a day (every 10-14 hours) for 12 weeks, in combination with pegylated interferon (Peg-IFN)-alfa-2a solution for subcutaneous injection at the dose of 180 microgram per week (mcg/week) and ribavirin (RBV) oral tablets at the dose of 1000-1200 mg/day for 24 or 48 weeks depending on the treatment response at week 4.
Total	All

Other Adverse Events

	T12(q8h)/PR	**T12(b.i.d.)/PR**	**Total**
Total, other (not including serious) adverse events			
# participants affected / at risk	**359/371 (96.77%)**	**358/369 (97.02%)**	**717/740 (96.89%)**
Blood and lymphatic system disorders			
Anaemia * 1			
# participants affected / at risk	**148/371 (39.89%)**	**155/369 (42.01%)**	**303/740 (40.95%)**
Neutropenia * 1			
# participants affected / at risk	**30/371 (8.09%)**	**36/369 (9.76%)**	**66/740 (8.92%)**
Thrombocytopenia * 1			
# participants affected / at risk	**30/371 (8.09%)**	**29/369 (7.86%)**	**59/740 (7.97%)**
Eye disorders			
Vision blurred * 1			
# participants affected / at risk	**17/371 (4.58%)**	**20/369 (5.42%)**	**37/740 (5.00%)**
Gastrointestinal disorders			
Nausea * 1			
# participants affected / at risk	**143/371 (38.54%)**	**129/369 (34.96%)**	**272/740 (36.76%)**
Diarrhoea * 1			

# participants affected / at risk	71/371 (19.14%)	49/369 (13.28%)	120/740 (16.22%)
Anal pruritus *1			
# participants affected / at risk	43/371 (11.59%)	30/369 (8.13%)	73/740 (9.86%)
Vomiting *1			
# participants affected / at risk	41/371 (11.05%)	38/369 (10.30%)	79/740 (10.68%)
Anorectal discomfort *1			
# participants affected / at risk	36/371 (9.70%)	39/369 (10.57%)	75/740 (10.14%)
Haemorrhoids *1			
# participants affected / at risk	33/371 (8.89%)	26/369 (7.05%)	59/740 (7.97%)
Dry mouth *1			
# participants affected / at risk	23/371 (6.20%)	24/369 (6.50%)	47/740 (6.35%)
Dyspepsia *1			
# participants affected / at risk	22/371 (5.93%)	15/369 (4.07%)	37/740 (5.00%)
Proctalgia *1			
# participants affected / at risk	21/371 (5.66%)	18/369 (4.88%)	39/740 (5.27%)
Abdominal pain *1			
# participants affected / at risk	19/371 (5.12%)	10/369 (2.71%)	29/740 (3.92%)
General disorders			
Fatigue *1			
# participants affected / at risk	178/371 (47.98%)	173/369 (46.88%)	351/740 (47.43%)
Pyrexia *1			
# participants affected / at risk	78/371 (21.02%)	62/369 (16.80%)	140/740 (18.92%)
Asthenia *1			
# participants affected / at risk	72/371 (19.41%)	65/369 (17.62%)	137/740 (18.51%)
Influenza like illness *1			
# participants affected / at risk	60/371 (16.17%)	75/369 (20.33%)	135/740 (18.24%)
Chills *1			
# participants affected / at risk	43/371 (11.59%)	22/369 (5.96%)	65/740 (8.78%)
Injection site reaction *1			
# participants affected / at risk	25/371 (6.74%)	23/369 (6.23%)	48/740 (6.49%)
Metabolism and nutrition disorders			
Anorexia *1			
# participants affected / at risk	36/371 (9.70%)	30/369 (8.13%)	66/740 (8.92%)
Decreased appetite *1			
# participants affected / at risk	19/371 (5.12%)	22/369 (5.96%)	41/740 (5.54%)
Musculoskeletal and connective tissue disorders			
Myalgia *1			
# participants affected / at risk	41/371 (11.05%)	33/369 (8.94%)	74/740 (10.00%)
Arthralgia *1			
# participants affected / at risk	24/371 (6.47%)	25/369 (6.78%)	49/740 (6.62%)
Nervous system disorders			
Headache *1			
# participants affected / at risk	108/371 (29.11%)	87/369 (23.58%)	195/740 (26.35%)
Dysgeusia *1			
# participants affected / at risk	46/371 (12.40%)	36/369 (9.76%)	82/740 (11.08%)
Dizziness *1			
# participants affected / at risk	30/371 (8.09%)	41/369 (11.11%)	71/740 (9.59%)
Psychiatric disorders			
Insomnia *1			
# participants affected / at risk	68/371 (18.33%)	69/369 (18.70%)	137/740 (18.51%)

Mood altered *1			
# participants affected / at risk	**47/371 (12.67%)**	**37/369 (10.03%)**	**84/740 (11.35%)**
Depression *1			
# participants affected / at risk	**36/371 (9.70%)**	**27/369 (7.32%)**	**63/740 (8.51%)**
Anxiety *1			
# participants affected / at risk	**20/371 (5.39%)**	**26/369 (7.05%)**	**46/740 (6.22%)**
Respiratory, thoracic and mediastinal disorders			
Dyspnoea *1			
# participants affected / at risk	**44/371 (11.86%)**	**39/369 (10.57%)**	**83/740 (11.22%)**
Cough *1			
# participants affected / at risk	**35/371 (9.43%)**	**36/369 (9.76%)**	**71/740 (9.59%)**
Dyspnoea exertional *1			
# participants affected / at risk	**19/371 (5.12%)**	**17/369 (4.61%)**	**36/740 (4.86%)**
Skin and subcutaneous tissue disorders			
Pruritus *1			
# participants affected / at risk	**158/371 (42.59%)**	**158/369 (42.82%)**	**316/740 (42.70%)**
Rash *1			
# participants affected / at risk	**133/371 (35.85%)**	**129/369 (34.96%)**	**262/740 (35.41%)**
Dry skin *1			
# participants affected / at risk	**35/371 (9.43%)**	**43/369 (11.65%)**	**78/740 (10.54%)**
Erythema *1			
# participants affected / at risk	**22/371 (5.93%)**	**20/369 (5.42%)**	**42/740 (5.68%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 11.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** If the PI (Investigator) wishes to publish information from the study, a copy of the manuscript must be provided to the sponsor for review at least 60 days before submission for publication or presentation. If requested by the sponsor in writing, the investigator will withhold such publication for up to an additional 60 days.

Results Point of Contact:

Name/Title: Compound Development Team Leader
Organization: Janssen Infectious Diseases BVBA
phone: 32 14 64 13 70

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Sarrazin C, Dierynck I, Cloherty G, Ghys A, Janssen K, Luo D, Witek J, Buti M, Picchio G, De Meyer S. An OPTIMIZE study retrospective analysis for management of telaprevir-treated hepatitis C virus (HCV)-infected patients by use of the Abbott RealTime HCV RNA assay. J Clin Microbiol. 2015 Apr;53(4):1264-9. doi: 10.1128/JCM.03030-14. Epub 2015 Feb 4.

Buti M, Agarwal K, Horsmans Y, Sievert W, Janczewska E, Zeuzem S, Nyberg L, Brown RS Jr, Hézode C, Rizzetto M, Paraná R, De Meyer S, De Masi R, Luo D, Bertelsen K, Witek J. Telaprevir twice daily is noninferior to telaprevir every 8 hours for patients with chronic hepatitis C. Gastroenterology. 2014 Mar;146(3):744-753.e3. doi: 10.1053/j.gastro.2013.11.047. Epub 2013 Dec 4.

Responsible Party:	Janssen Infectious Diseases BVBA
ClinicalTrials.gov Identifier:	NCT01241760 History of Changes
Other Study ID Numbers:	**CR013711** OPTIMIZE-HCV (Other Identifier: Janssen Infectious Diseases BVBA) VX-950-C211 (Other Identifier: Janssen Infectious Diseases BVBA) 2010-021628-84 (EudraCT Number)
Study First Received:	October 28, 2010
Results First Received:	September 23, 2013
Last Updated:	May 14, 2014
Health Authority:	United States: Food and Drug Administration USA: FOOD AND DRUG ADMINISTRATION - CENTER FOR DRUG EVALUATION AND RESEARCH Germany: Ethics Commission Great Britain: Medicines and Healthcare Products Regulatory Agency Ireland: Irish Medicines Board

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