ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: July 9, 2014

ClinicalTrials.gov ID: NCT00535847

Study Identification

Unique Protocol ID: VX06-950-107

Brief Title: A Rollover Study for Subjects Participating in the Control Arm of Study VX06-950-106, VX05-950-104 and VX05-950-104EU Whose Plasma Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Levels Did Not Respond to Therapy

Official Title: A Phase 2 Rollover Protocol of Telaprevir (VX-950) in Combination With Peginterferon Alfa-2a (Pegasys®) and Ribavirin (Copegus®) in Subjects Enrolled in the Control Group (Group A) of Study VX06-950-106, VX05-950-104 and VX05-950-104EU Who Did Not Achieve or Maintain an Undetectable HCV RNA Level Through Sustained Viral Response

Secondary IDs:

Study Status

Record Verification: July 2014

Overall Status: Completed

Study Start: October 2007

Primary Completion: February 2010 [Actual]

Study Completion: February 2010 [Actual]

Sponsor/Collaborators

Sponsor: Vertex Pharmaceuticals Incorporated

Responsible Party: Sponsor

Collaborators: Tibotec, Inc

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No
IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CDER IND/IDE Number: 71,832 Serial Number: 0000 Has Expanded Access? No
Review Board:	Approval Status: Approved Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	Yes
Plan to Share IPD?:	
Oversight Authorities:	United States: Food and Drug Administration Canada: Health Canada Germany: Federal Institute for Drugs and Medical Devices Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) United Kingdom: Medicines and Healthcare Products Regulatory Agency

Study Description

Brief Summary:	To provide access to a telaprevir-based treatment to subjects of the Control Group of Study VX06-950-106 (NCT00420784), VX05-950-104 (NCT00336479), and VX05-950-104EU (NCT00372385) who stopped treatment due to inadequate response to treatment. Safety, tolerability, and Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) levels will be collected.
Detailed Description:	

Conditions

Conditions:	Hepatitis C
Keywords:	Genotype 1

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Parallel Assignment
Number of Arms:	3
Masking:	Open Label
Allocation:	Non-Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	117 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week Telaprevir 750 mg tablet thrice daily for 12 weeks in combination with pegylated interferon alfa 2a (Peg-IFN-alfa-2a) 180 microgram per week (mcg/week) subcutaneous injection and ribavirin (RBV) tablet orally twice daily at a dose of 1000 milligram per day (mg/day) for subjects weighing less than (<) 75 kilogram (kg) and 1200 mg/day for subjects weighing greater than or equal to (>=) 75 kg, for 24 weeks.	Drug: Telaprevir Tablet Other Names: • VX-950 Drug: Ribavirin Tablet Drug: Pegylated interferon alfa 2a Solution for Injection
Experimental: Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week Telaprevir 750 mg tablet thrice daily for 12 weeks in combination with Peg-IFN-alfa-2a 180 mcg/week subcutaneous injection and RBV tablet orally twice daily at a dose of 1000 mg/day for subjects weighing <75 kg and 1200 mg/day for subjects weighing >=75 kg, for 48 weeks.	Drug: Telaprevir Tablet Other Names: • VX-950 Drug: Ribavirin Tablet Drug: Pegylated interferon alfa 2a Solution for Injection
Experimental: Other Subjects received telaprevir 750 mg tablet thrice daily in combination with Peg-IFN-alfa-2a 180 mcg/week subcutaneous injection and RBV tablet orally twice daily at a dose of 1000 mg/day for subjects <75 kg and 1200 mg/day for subjects weighing >=75 kg, discontinued treatment before Week 12 in this study (VX06-950-107 [NCT00535847]) and had	Drug: Telaprevir Tablet Other Names: • VX-950 Drug: Ribavirin

Arms	Assigned Interventions
a partial response, viral breakthrough, or relapse in the parent study (VX05-950-104 [NCT00336479], VX05-950-104EU [NCT00372385] or VX06-950-106 [NCT00420784]) were included in "Other" reporting group.	Tablet Drug: Pegylated interferon alfa 2a Solution for Injection

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 70 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Enrolled in the control arm of Study VX06-950-106 (NCT00420784), VX05-950-104 (NCT00336479) or VX05-950-104EU (NCT00372385)

Contacts/Locations

Study Officials: Nathalie Adda, MD
Study Director
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Locations: United States, Alabama
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United States, California
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Los Angeles, California, United States

United States, Florida
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United States, Maryland
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United States, Michigan
Henry Ford Hospital
Detroit, Michigan, United States

United States, Missouri
St Louis University
St Louis, Missouri, United States

United States, North Carolina
Duke University Medical Center
Durham, North Carolina, United States

United States, New Mexico
University of New Mexico
Albuquerque, New Mexico, United States

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New York, New York, United States

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Rotterdam, Netherlands

Academic Medical Center
Amsterdam, Netherlands

Leiden University Medical Center
Leiden, Netherlands

Canada, Ontario
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Bonn, Germany

Austria

Vienna, Austria

United Kingdom
London, United Kingdom

France
Vandoeuvre, France

Nice, France

Paris, France

Pessac, France

Lyon, France

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	Subjects randomized to placebo control group in parent studies VX05-950-104 (NCT00336479), VX05-950-104EU (NCT00372385) and VX06-950-106 (NCT00420784) who had discontinued treatment in the parent study due to an inadequate response to treatment or relapsed after treatment were eligible to participate in this study VX06-950-107 (NCT00535847).

Reporting Groups

	Description
Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week	Telaprevir 750 mg tablet thrice daily for 12 weeks in combination with pegylated interferon alfa 2a (Peg-IFN-alfa-2a) 180 microgram per week (mcg/week) subcutaneous injection and ribavirin (RBV) tablet orally twice daily at a dose of 1000 milligram per day (mg/day) for subjects weighing less than (<) 75 kilogram (kg) and 1200 mg/day for subjects weighing greater than or equal to (>=) 75 kg, for 24 weeks.

	Description
Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week	Telaprevir 750 mg tablet thrice daily for 12 weeks in combination with Peg-IFN-alfa-2a 180 mcg/week subcutaneous injection and RBV tablet orally twice daily at a dose of 1000 mg/day for subjects weighing <75 kg and 1200 mg/day for subjects weighing >=75 kg, for 48 weeks.
Other	Subjects received telaprevir 750 mg tablet thrice daily in combination with Peg-IFN-alfa-2a 180 mcg/week subcutaneous injection and RBV tablet orally twice daily at a dose of 1000 mg/day for subjects <75 kg and 1200 mg/day for subjects weighing >=75 kg, discontinued treatment before Week 12 in this study (VX06-950-107 [NCT00535847]) and had a partial response, viral breakthrough, or relapse in the parent study (VX05-950-104 [NCT00336479], VX05-950-104EU [NCT00372385] or VX06-950-106 [NCT00420784]) were included in "Other" reporting group.

Overall Study

	Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week	Other
Started	81	34	2
Completed	59	20	0
Not Completed	22	14	2
Adverse Event	5	3	2
Non compliance	1	1	0
Protocol-defined Virologic Stopping Rule	16	10	0

Baseline Characteristics

Baseline Analysis Population Description

The full analysis (FA) set included all enrolled subjects who received at least 1 dose of study drug in this study (VX06-950-107 [NCT00535847]).

Reporting Groups

	Description
Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week	Telaprevir 750 mg tablet thrice daily for 12 weeks in combination with pegylated interferon alfa 2a (Peg-IFN-alfa-2a) 180 microgram per week (mcg/week) subcutaneous injection and ribavirin (RBV) tablet orally twice daily at a dose of 1000 milligram per day (mg/day) for subjects weighing less than (<) 75 kilogram (kg) and 1200 mg/day for subjects weighing greater than or equal to (>=) 75 kg, for 24 weeks.

	Description
Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week	Telaprevir 750 mg tablet thrice daily for 12 weeks in combination with Peg-IFN-alfa-2a 180 mcg/week subcutaneous injection and RBV tablet orally twice daily at a dose of 1000 mg/day for subjects weighing <75 kg and 1200 mg/day for subjects weighing >=75 kg, for 48 weeks.
Other	Subjects received telaprevir 750 mg tablet thrice daily in combination with Peg-IFN-alfa-2a 180 mcg/week subcutaneous injection and RBV tablet orally twice daily at a dose of 1000 mg/day for subjects <75 kg and 1200 mg/day for subjects weighing >=75 kg, discontinued treatment before Week 12 in this study (VX06-950-107 [NCT00535847]) and had a partial response, viral breakthrough, or relapse in the parent study (VX05-950-104 [NCT00336479], VX05-950-104EU [NCT00372385] or VX06-950-106 [NCT00420784]) were included in "Other" reporting group.

Baseline Measures

		Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week	Other	Total
Overall Number of Participants		81	34	2	117
Age, Categorical Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	81 participants	34 participants	2 participants	117 participants
	<=18 years	0 0%	0 0%	0 0%	0 0%
	Between 18 and 65 years	81 100%	34 100%	2 100%	117 100%
	>=65 years	0 0%	0 0%	0 0%	0 0%
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	81 participants	34 participants	2 participants	117 participants
		50.0 (7.7)	51.2 (5.9)	49.0 (0.0)	50.3 (7.2)
Gender, Male/ Female Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	81 participants	34 participants	2 participants	117 participants
	Female	28 34.57%	8 23.53%	0 0%	36 30.77%
	Male	53 65.43%	26 76.47%	2 100%	81 69.23%

		Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week	Other	Total
Region of Enrollment Measure Type: Number Unit of measure: participants	Number Analyzed	81 participants	34 participants	2 participants	117 participants
North America		64	26	2	92
Europe		17	8	0	25

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Subjects With Undetectable Plasma Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) at Week 24 After the Completion of Treatment
Measure Description	The plasma HCV RNA level was measured using Roche TaqMan HCV RNA assay. The lower limit of detection was 10 international units per milliliter (IU/mL).
Time Frame	24 weeks after the completion of treatment (up to Week 72)
Safety Issue?	No

Analysis Population Description

The FA set included all enrolled subjects who received at least 1 dose of study drug in this study (VX06-950-107 [NCT00535847]).

Reporting Groups

	Description
Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week	Telaprevir 750 mg tablet thrice daily for 12 weeks in combination with pegylated interferon alfa 2a (Peg-IFN-alfa-2a) 180 microgram per week (mcg/week) subcutaneous injection and ribavirin (RBV) tablet orally twice daily at a dose of 1000 milligram per day (mg/day) for subjects weighing less than (<) 75 kilogram (kg) and 1200 mg/day for subjects weighing greater than or equal to (>=) 75 kg, for 24 weeks.
Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week	Telaprevir 750 mg tablet thrice daily for 12 weeks in combination with Peg-IFN-alfa-2a 180 mcg/week subcutaneous injection and RBV tablet orally twice daily at a dose of 1000 mg/day for subjects weighing <75 kg and 1200 mg/day for subjects weighing >=75 kg, for 48 weeks.

	Description
Other	Subjects received telaprevir 750 mg tablet thrice daily in combination with Peg-IFN-alfa-2a 180 mcg/week subcutaneous injection and RBV tablet orally twice daily at a dose of 1000 mg/day for subjects <75 kg and 1200 mg/day for subjects weighing >=75 kg, discontinued treatment before Week 12 in this study (VX06-950-107 [NCT00535847]) and had a partial response, viral breakthrough, or relapse in the parent study (VX05-950-104 [NCT00336479], VX05-950-104EU [NCT00372385] or VX06-950-106 [NCT00420784]) were included in "Other" reporting group.

Measured Values

	Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week	Other
Number of Participants Analyzed	81	34	2
Percentage of Subjects With Undetectable Plasma Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) at Week 24 After the Completion of Treatment Number (95% Confidence Interval) Unit of measure: percentage of participants	60.5 (49.0 to 71.2)	52.9 (35.1 to 70.2)	100.0 (15.8 to 100.0)

2. Primary Outcome Measure:

Measure Title	Number of Subjects With Adverse Events (AEs) and Serious Adverse Events (SAEs)
Measure Description	AE: any adverse change from the subject's baseline (pre-treatment) condition, including any adverse experience, abnormal recording or clinical laboratory assessment value which occurs during the course of the study, whether it is considered related to the study drug or not. An adverse event includes any newly occurring event or previous condition that has increased in severity or frequency since the administration of study drug. SAE: medical event or condition, which falls into any of the following categories, regardless of its relationship to the study drug: death, life threatening adverse experience, in-patient hospitalization/prolongation of hospitalization, persistent/significant disability or incapacity, congenital anomaly/birth defect, important medical event. "Study drug" includes all investigational agents (including placebo, if applicable) administered during the course of the study.
Time Frame	Baseline through Week 48
Safety Issue?	Yes

Analysis Population Description

The FA set included all enrolled subjects who received at least 1 dose of study drug in this study (VX06-950-107 [NCT00535847]).

Reporting Groups

	Description
Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week	Telaprevir 750 mg tablet thrice daily for 12 weeks in combination with pegylated interferon alfa 2a (Peg-IFN-alfa-2a) 180 microgram per week (mcg/week) subcutaneous injection and ribavirin (RBV) tablet orally twice daily at a dose of 1000 milligram per day (mg/day) for subjects weighing less than (<) 75 kilogram (kg) and 1200 mg/day for subjects weighing greater than or equal to (>=) 75 kg, for 24 weeks.
Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week	Telaprevir 750 mg tablet thrice daily for 12 weeks in combination with Peg-IFN-alfa-2a 180 mcg/week subcutaneous injection and RBV tablet orally twice daily at a dose of 1000 mg/day for subjects weighing <75 kg and 1200 mg/day for subjects weighing >=75 kg, for 48 weeks.
Other	Subjects received telaprevir 750 mg tablet thrice daily in combination with Peg-IFN-alfa-2a 180 mcg/week subcutaneous injection and RBV tablet orally twice daily at a dose of 1000 mg/day for subjects <75 kg and 1200 mg/day for subjects weighing >=75 kg, discontinued treatment before Week 12 in this study (VX06-950-107 [NCT00535847]) and had a partial response, viral breakthrough, or relapse in the parent study (VX05-950-104 [NCT00336479], VX05-950-104EU [NCT00372385] or VX06-950-106 [NCT00420784]) were included in "Other" reporting group.

Measured Values

	Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week	Other
Number of Participants Analyzed	81	34	2
Number of Subjects With Adverse Events (AEs) and Serious Adverse Events (SAEs) Measure Type: Number Unit of measure: participants			
AEs	77	31	2
SAEs	7	3	1

3. Secondary Outcome Measure:

Measure Title	Percentage of Prior Relapsers With Undetectable HCV RNA
Measure Description	Prior relapsers: subjects who had undetectable HCV RNA at the end of treatment in parent study but reverted to detectable levels of HCV RNA after stopping treatment in parent study were categorized as prior relapsers. Percentage of prior relapsers with undetectable HCV RNA 24 weeks after the completion of treatment in this study were presented. The plasma HCV RNA level was measured using Roche TaqMan HCV RNA assay. The lower limit of detection was 10 international units per milliliter (IU/mL).
Time Frame	24 weeks after the completion of treatment (up to Week 72)

Safety Issue?	No

Analysis Population Description

Analysis population included all enrolled subjects who were prior relapsers in parent study (VX05-950-104 [NCT00336479], VX05-950-104EU [NCT00372385] or VX06-950-106 [NCT00420784]) and received at least 1 dose of study drug in this study (VX06-950-107 [NCT00535847]).

Reporting Groups

	Description
Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week	Telaprevir 750 mg tablet thrice daily for 12 weeks in combination with pegylated interferon alfa 2a (Peg-IFN-alfa-2a) 180 microgram per week (mcg/week) subcutaneous injection and ribavirin (RBV) tablet orally twice daily at a dose of 1000 milligram per day (mg/day) for subjects weighing less than (<) 75 kilogram (kg) and 1200 mg/day for subjects weighing greater than or equal to (>=) 75 kg, for 24 weeks.
Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week	Telaprevir 750 mg tablet thrice daily for 12 weeks in combination with Peg-IFN-alfa-2a 180 mcg/week subcutaneous injection and RBV tablet orally twice daily at a dose of 1000 mg/day for subjects weighing <75 kg and 1200 mg/day for subjects weighing >=75 kg, for 48 weeks.
Other	Subjects received telaprevir 750 mg tablet thrice daily in combination with Peg-IFN-alfa-2a 180 mcg/week subcutaneous injection and RBV tablet orally twice daily at a dose of 1000 mg/day for subjects <75 kg and 1200 mg/day for subjects weighing >=75 kg, discontinued treatment before Week 12 in this study (VX06-950-107 [NCT00535847]) and had a partial response, viral breakthrough, or relapse in the parent study (VX05-950-104 [NCT00336479], VX05-950-104EU [NCT00372385] or VX06-950-106 [NCT00420784]) were included in "Other" reporting group.

Measured Values

	Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week	Other
Number of Participants Analyzed	25	3	1
Percentage of Prior Relapsers With Undetectable HCV RNA Number (95% Confidence Interval) Unit of measure: percentage of participants	96.0 (79.6 to 99.9)	100.0 (29.2 to 100.0)	100.0 (2.5 to 100.0)

4. Secondary Outcome Measure:

Measure Title	Percentage of Subjects With End of Treatment Response

Measure Description	Subjects were considered to have an end of treatment response if they completed the assigned treatment regimen and had undetectable HCV RNA at end of treatment or prematurely discontinued the assigned treatment regimen and had undetectable HCV RNA at the time of discontinuation. The plasma HCV RNA level was measured using Roche TaqMan HCV RNA assay. The lower limit of detection was 10 international units per milliliter (IU/mL).
Time Frame	End of treatment (up to Week 48)
Safety Issue?	No

Analysis Population Description

The FA set included all enrolled subjects who received at least 1 dose of study drug in this study (VX06-950-107 [NCT00535847]).

Reporting Groups

	Description
Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week	Telaprevir 750 mg tablet thrice daily for 12 weeks in combination with pegylated interferon alfa 2a (Peg-IFN-alfa-2a) 180 microgram per week (mcg/week) subcutaneous injection and ribavirin (RBV) tablet orally twice daily at a dose of 1000 milligram per day (mg/day) for subjects weighing less than (<) 75 kilogram (kg) and 1200 mg/day for subjects weighing greater than or equal to (>=) 75 kg, for 24 weeks.
Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week	Telaprevir 750 mg tablet thrice daily for 12 weeks in combination with Peg-IFN-alfa-2a 180 mcg/week subcutaneous injection and RBV tablet orally twice daily at a dose of 1000 mg/day for subjects weighing <75 kg and 1200 mg/day for subjects weighing >=75 kg, for 48 weeks.
Other	Subjects received telaprevir 750 mg tablet thrice daily in combination with Peg-IFN-alfa-2a 180 mcg/week subcutaneous injection and RBV tablet orally twice daily at a dose of 1000 mg/day for subjects <75 kg and 1200 mg/day for subjects weighing >=75 kg, discontinued treatment before Week 12 in this study (VX06-950-107 [NCT00535847]) and had a partial response, viral breakthrough, or relapse in the parent study (VX05-950-104 [NCT00336479], VX05-950-104EU [NCT00372385] or VX06-950-106 [NCT00420784]) were included in "Other" reporting group.

Measured Values

	Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week	Other
Number of Participants Analyzed	81	34	2
Percentage of Subjects With End of Treatment Response Number (95% Confidence Interval) Unit of measure: percentage of participants	72.8 (61.8 to 82.1)	64.7 (46.5 to 80.3)	100.0 (15.8 to 100.0)

5. Secondary Outcome Measure:

Measure Title	Percentage of Subjects With Undetectable HCV RNA at Week 48 After Completion of Treatment Among Subjects Who Completed Assigned Treatment
Measure Description	The plasma HCV RNA level was measured using Roche TaqMan HCV RNA assay. The lower limit of detection was 10 international units per milliliter (IU/mL).
Time Frame	48 weeks after completion of treatment (up to Week 96)
Safety Issue?	No

Analysis Population Description

Analysis population included subjects who completed assigned treatment in this study (VX06-950-107 [NCT00535847]).

Reporting Groups

	Description
Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week	Telaprevir 750 mg tablet thrice daily for 12 weeks in combination with pegylated interferon alfa 2a (Peg-IFN-alfa-2a) 180 microgram per week (mcg/week) subcutaneous injection and ribavirin (RBV) tablet orally twice daily at a dose of 1000 milligram per day (mg/day) for subjects weighing less than (<) 75 kilogram (kg) and 1200 mg/day for subjects weighing greater than or equal to (>=) 75 kg, for 24 weeks.
Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week	Telaprevir 750 mg tablet thrice daily for 12 weeks in combination with Peg-IFN-alfa-2a 180 mcg/week subcutaneous injection and RBV tablet orally twice daily at a dose of 1000 mg/day for subjects weighing <75 kg and 1200 mg/day for subjects weighing >=75 kg, for 48 weeks.
Other	Subjects received telaprevir 750 mg tablet thrice daily in combination with Peg-IFN-alfa-2a 180 mcg/week subcutaneous injection and RBV tablet orally twice daily at a dose of 1000 mg/day for subjects <75 kg and 1200 mg/day for subjects weighing >=75 kg, discontinued treatment before Week 12 in this study (VX06-950-107 [NCT00535847]) and had a partial response, viral breakthrough, or relapse in the parent study (VX05-950-104 [NCT00336479], VX05-950-104EU [NCT00372385] or VX06-950-106 [NCT00420784]) were included in "Other" reporting group.

Measured Values

	Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week	Other
Number of Participants Analyzed	59	20	0
Percentage of Subjects With Undetectable HCV RNA at Week 48 After Completion of Treatment Among Subjects Who Completed Assigned Treatment Number (95% Confidence Interval) Unit of measure: percentage of participants	83.1 (71.0 to 91.6)	70.0 (45.7 to 88.1)	---

6. Secondary Outcome Measure:

Measure Title	Cross Tabulation of Extended Rapid Viral Response (eRVR) and Sustained Viral Response (SVR) in With Prior Response
Measure Description	Cross tabulation of number of subjects with eRVR/SVR status in present study was presented with respect to prior response status of subjects in parent studies. eRVR=undetectable HCV RNA at Week 4 and Week 12, SVR=undetectable HCV RNA at end of treatment (EOT) and at 24 weeks after last dose of study treatment without any confirmed detectable HCV RNA in between. Prior response=subjects were categorized into following categories based on their viral response in the parent study: Null Response (less than [<] 1-log10 decrease in HCV RNA at Week 4 or <2-log10 decrease in HCV RNA at Week 12), Partial Response (greater than [>] 2-log10 decrease in HCV RNA at Week 12, but detectable HCV RNA at Week 24), Viral Breakthrough (detectable HCV RNA during treatment after achieving undetectable HCV RNA), Relapse (undetectable HCV RNA at EOT but detectable HCV RNA during viral follow-up). Plasma HCV RNA level was measured using Roche TaqMan HCV RNA assay; lower limit of detection=10 IU/mL.
Time Frame	Baseline up to Week 72
Safety Issue?	No

Analysis Population Description

The FA set included subjects who received at least 1 dose of study drug in this study (VX06-950-107 [NCT00535847]). Data was presented for overall subjects based on eRVR and SVR status as per planned analysis.

Reporting Groups

	Description
Achieved eRVR/Achieved SVR	All subjects in “Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week”, “Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week” and “Other” reporting groups who achieved eRVR and SVR in this study (VX06-950-107 [NCT00535847]).
Achieved eRVR/Did Not Achieve SVR	All subjects in “Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week”, “Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week” and “Other” reporting groups who achieved eRVR but did not achieve SVR in this study (VX06-950-107 [NCT00535847]).
Did Not Achieve eRVR/Achieved SVR	All subjects in “Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week”, “Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week” and “Other” reporting groups who did not achieve eRVR but achieved SVR in this study (VX06-950-107 [NCT00535847]).
Did Not Achieve eRVR/Did Not Achieve SVR	All subjects in “Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week”, “Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week” and “Other” reporting groups who neither achieved eRVR nor SVR in this study (VX06-950-107 [NCT00535847]).

Measured Values

	Achieved eRVR/ Achieved SVR	Achieved eRVR/Did Not Achieve SVR	Did Not Achieve eRVR/Achieved SVR	Did Not Achieve eRVR/Did Not Achieve SVR
Number of Participants Analyzed	57	12	12	36
Cross Tabulation of Extended Rapid Viral Response (eRVR) and Sustained Viral Response (SVR) in With Prior Response Measure Type: Number Unit of measure: participants				
Prior Null Response	12	5	7	27
Prior Partial Response	15	7	1	6
Prior Viral Breakthrough	6	0	0	2
Prior Relapse	24	0	4	1

Statistical Analysis 1 for Cross Tabulation of Extended Rapid Viral Response (eRVR) and Sustained Viral Response (SVR) in With Prior Response

Statistical Analysis Overview	Comparison Groups	Achieved eRVR/Achieved SVR, Achieved eRVR/Did Not Achieve SVR, Did Not Achieve eRVR/ Achieved SVR, Did Not Achieve eRVR/Did Not Achieve SVR
	Comments	Stratified Analysis (Mantel-Haenszel)- The Mantel-Haenszel estimator provides an estimate of the common odds ratio for the association between eRVR and SVR across the prior response strata.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	12.703
	Confidence Interval	(2-Sided) 95% 4.259 to 37.884
	Estimation Comments	[Not specified]

Reported Adverse Events

Time Frame	Adverse Events during Overall Treatment Phase (Baseline through Week 48)
Additional Description	In the event a single participant has experienced both a serious and a non-serious form of the same adverse event term, the individual has been included in the numerator ("number of affected participants") of both adverse event tables.

Reporting Groups

	Description
Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week	Telaprevir 750 mg tablet thrice daily for 12 weeks in combination with pegylated interferon alfa 2a (Peg-IFN-alfa-2a) 180 microgram per week (mcg/week) subcutaneous injection and ribavirin (RBV) tablet orally twice daily at a dose of 1000 milligram per day (mg/day) for subjects weighing less than (<) 75 kilogram (kg) and 1200 mg/day for subjects weighing greater than or equal to (>=) 75 kg, for 24 weeks.
Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week	Telaprevir 750 mg tablet thrice daily for 12 weeks in combination with Peg-IFN-alfa-2a 180 mcg/week subcutaneous injection and RBV tablet orally twice daily at a dose of 1000 mg/day for subjects weighing <75 kg and 1200 mg/day for subjects weighing >=75 kg, for 48 weeks.
Other	Subjects received telaprevir 750 mg tablet thrice daily in combination with Peg-IFN-alfa-2a 180 mcg/week subcutaneous injection and RBV tablet orally twice daily at a dose of 1000 mg/day for subjects <75 kg and 1200 mg/day for subjects weighing >=75 kg, discontinued treatment before Week 12 in this study (VX06-950-107 [NCT00535847]) and had a partial response, viral breakthrough, or relapse in the parent study (VX05-950-104 [NCT00336479], VX05-950-104EU [NCT00372385] or VX06-950-106 [NCT00420784]) were included in "Other" reporting group.

Serious Adverse Events

	Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week	Other
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	7/81 (8.64%)	3/34 (8.82%)	1/2 (50%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 24 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a,RBV 48 Week	Other
Total	77/81 (95.06%)	31/34 (91.18%)	2/2 (100%)

More Information

Certain Agreements:

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

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 from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

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