ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: September 30, 2013

ClinicalTrials.gov ID: NCT00758043

Study Identification

Unique Protocol ID:	VX08-950-111
Brief Title:	A Study Evaluating 24-Week and 48-Week Telaprevir-Based Regimen in Treatment Naïve Subjects With Genotype 1 Chronic Hepatitis C Who Achieve an Extended Rapid Viral Response
Official Title:	A Randomized Study of Stopping Treatment at 24 Weeks or Continuing Treatment to 48 Weeks in Treatment-Naïve Subjects With Genotype 1 Chronic Hepatitis C Who Achieve an Extended Rapid Viral Response While Receiving Telaprevir, Peginterferon Alfa2a (Pegasys®) and Ribavirin (Copegus®)
Secondary IDs:	EudraCT 2008-003836-39

Study Status

Record Verification:	June 2011
Overall Status:	Completed
Study Start:	October 2008
Primary Completion:	June 2010 [Actual]
Study Completion:	July 2010 [Actual]

Sponsor/Collaborators

Sponsor:	Vertex Pharmaceuticals Incorporated
Responsible Party:	Sponsor
Collaborators:	Tibotec Pharmaceutical Limited

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: 071832 Serial Number: 0205 Has Expanded Access? No
Review Board:	Approval Status: Approved Approval Number: 24070 Board Name: Quorum Review, Inc Board Affiliation: Quorum Review, Inc Phone: 206-448-4082 Email:
Data Monitoring?:	Yes
Plan to Share IPD?:	
Oversight Authorities:	United States: Food and Drug Administration Belgium: Federal Agency for Medicinal Products and Health Products Netherlands: The Central Committee on Research Involving Human Subjects (CCMO)

Study Description

Brief Summary:	This study is being conducted to learn more about the safety and effect of telaprevir in combination with peginterferon alfa-2a (PEG-IFN) and ribavirin (RBV) in participants with hepatitis C who have never been treated for their hepatitis C virus (HCV). The study is designed to look at the relative benefits of 24 or 48 weeks of total treatment in people who respond quickly to a telaprevir-based treatment.
Detailed Description:	

Conditions

Conditions:	Hepatitis C
Keywords:	Genotype 1

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	4
Masking:	Open Label
Allocation:	Randomized
Endpoint Classification:	
Enrollment:	540 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: T12PR24 (eRVR+) Randomized Group: Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by Peg-IFN-alfa-2a + RBV for 12 weeks; subjects achieved an extended rapid viral response (eRVR+) and were randomized to this group	Drug: telaprevir 750 mg every 8 hours (q8h) for 12 weeks Other Names: • VX-950 Drug: ribavirin 1000 - 1200 mg/day based on body weight for either 24 or 48 weeks Other Names: • Copegus Biological/Vaccine: peginterferon alfa-2a 180 mcg/week for either 24 or 48 weeks Other Names: • Pegasys
Experimental: T12PR48 (eRVR+) Randomized Group: Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by Peg-IFN-alfa-2a + RBV for 36 weeks; subjects achieved an extended rapid viral response (eRVR+) and were randomized to this group	Drug: telaprevir 750 mg every 8 hours (q8h) for 12 weeks Other Names: • VX-950 Drug: ribavirin 1000 - 1200 mg/day based on body weight for either 24 or 48 weeks Other Names: • Copegus

Arms	Assigned Interventions
	Biological/Vaccine: peginterferon alfa-2a 180 mcg/week for either 24 or 48 weeks Other Names: • Pegasys
Experimental: T12PR48 (eRVR-) Assigned Group: Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by Peg-IFN-alfa-2a + RBV for 36 weeks; subjects did not achieve an extended rapid viral response and were assigned to this group	Drug: telaprevir 750 mg every 8 hours (q8h) for 12 weeks Other Names: • VX-950 Drug: ribavirin 1000 - 1200 mg/day based on body weight for either 24 or 48 weeks Other Names: • Copegus Biological/Vaccine: peginterferon alfa-2a 180 mcg/week for either 24 or 48 weeks Other Names: • Pegasys
Experimental: Other Other Group: Subjects who received at least 1 dose of study drug, but prematurely discontinued treatment before Week 20, were not randomized or assigned to a treatment regimen.	Drug: telaprevir 750 mg every 8 hours (q8h) for 12 weeks Other Names: • VX-950 Drug: ribavirin 1000 - 1200 mg/day based on body weight for either 24 or 48 weeks Other Names: • Copegus Biological/Vaccine: peginterferon alfa-2a 180 mcg/week for either 24 or 48 weeks Other Names: • Pegasys

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 70 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Has not received any previous treatment with any approved or investigational drug or drug regimen for the treatment of hepatitis C
- Male and female subjects, 18 to 70 years of age, inclusive
- Genotype 1, chronic hepatitis C with detectable HCV RNA.
- Screening laboratory values, tests, and physical exam within acceptable ranges
- Able and willing to follow contraception requirements
- Able to read and understand, and willing to sign the informed consent form and abide by the study restrictions.

Exclusion Criteria:

- Subject has any contraindications to Pegasys® or Copegus® therapy
- Evidence of hepatic decompensation in cirrhotic subjects
- History of organ transplant
- History of, or any current medical condition which could impact the safety of the subject in participation in the study

Contacts/Locations

Study Officials: Michael Adler, MD, PhD
Study Principal Investigator
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Hendrik Reesink, MD, PhD
Study Principal Investigator
Academic Medical Center of the University of Amsterdam

Kenneth Sherman, MD, PhD
Study Principal Investigator
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Locations: United States, Alabama
Birmingham, Alabama, United States, 35209

Birmingham, Alabama, United States, 35294

United States, Arizona
Phoenix, Arizona, United States, 85054

United States, California

Fresno, California, United States, 93721

La Jolla, California, United States, 92037

Los Angeles, California, United States, 90048

Sacramento, California, United States, 95817

San Diego, California, United States, 92115

San Diego, California, United States, 92123

San Francisco, California, United States, 94115

San Francisco, California, United States, 94143

United States, Colorado

Aurora, Colorado, United States, 80045

United States, Connecticut

Farmington, Connecticut, United States, 06030

United States, District of Columbia

Washington, District of Columbia, United States, 20010

Washington, District of Columbia, United States, 20010

United States, Florida

Gainsville, Florida, United States, 32610

Jacksonville, Florida, United States, 32224

Miami, Florida, United States, 33136

Orlando, Florida, United States, 32803

Sarasota, Florida, United States, 34243

Wellington, Florida, United States, 33414

United States, Georgia

Atlanta, Georgia, United States, 30309

Atlanta, Georgia, United States, 30308

Marietta, Georgia, United States, 30060

United States, Hawaii
Honolulu, Hawaii, United States, 96817

United States, Illinois
Chicago, Illinois, United States, 60612

Chicago, Illinois, United States, 60611

Downers Grove, Illinois, United States, 60515

United States, Indiana
Indianapolis, Indiana, United States, 46202

United States, Louisiana
New Orleans, Louisiana, United States, 70112

United States, Maryland
Baltimore, Maryland, United States, 21287

Baltimore, Maryland, United States, 21201

Hyattsville, Maryland, United States, 20783

Laurel, Maryland, United States, 20707

United States, Massachusetts
Boston, Massachusetts, United States, 02215

Boston, Massachusetts, United States, 02111

Boston, Massachusetts, United States, 02114

Worcester, Massachusetts, United States, 01655

United States, Michigan
Detroit, Michigan, United States, 48202

Novi, Michigan, United States, 48377

United States, Minnesota
Rochester, Minnesota, United States, 55905

United States, Missouri
Kansas City, Missouri, United States, 64131

St. Louis, Missouri, United States, 63110

St. Louis, Missouri, United States, 63104

United States, New Hampshire
Lebanon, New Hampshire, United States, 03756

United States, New Jersey
Atlantic City, New Jersey, United States, 08401

Egg Harbor Township, New Jersey, United States, 08234

United States, New Mexico
Albuquerque, New Mexico, United States, 87131

United States, New York
Bayside, New York, United States, 11358

Bronx, New York, United States, 10467

Manhasset, New York, United States, 11030

New York, New York, United States, 10029

New York, New York, United States, 10021

New York, New York, United States, 10032

New York, New York, United States, 10016

United States, North Carolina
Chapel Hill, North Carolina, United States, 27599

Durham, North Carolina, United States, 27710

Statesville, North Carolina, United States, 28677

United States, Ohio
Cincinnati, Ohio, United States, 45267

Cincinnati, Ohio, United States, 45219

Cleveland, Ohio, United States, 44109

United States, Oregon
Portland, Oregon, United States, 97239

United States, Pennsylvania
Philadelphia, Pennsylvania, United States, 19141

United States, Rhode Island
Providence, Rhode Island, United States, 02905

United States, South Carolina
Columbia, South Carolina, United States, 29204

United States, Tennessee
Germantown, Tennessee, United States, 38138

United States, Texas
Dallas, Texas, United States, 75246

Dallas, Texas, United States, 75203

San Antonio, Texas, United States, 78215

United States, Utah
Salt Lake City, Utah, United States, 84132

United States, Virginia
Falls Church, Virginia, United States, 22042

United States, Washington
Seattle, Washington, United States, 98104

Tacoma, Washington, United States, 98405

United States, Wisconsin
Madison, Wisconsin, United States, 53792

Milwaukee, Wisconsin, United States, 53226

Belgium
Brussels, Belgium, B1200

Brussels, Belgium, B1070

Gent, Belgium, 9000

Liège 1, Belgium, 4000

Netherlands
Amsterdam, Netherlands, 1100 DE

Amsterdam, Netherlands, 1081 HV

Arnhem, Netherlands, 6815 AD

Puerto Rico
Santurce, Puerto Rico, 00909

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
T12PR24 (eRVR+)	Telaprevir + peginterferon-alfa-2a (Peg-IFN-alfa-2a) + ribavirin (RBV) for 12 weeks, followed by 12 weeks of Peg-IFN-alfa-2a and RBV; subjects achieved an extended rapid viral response (eRVR+) and were randomized to this group
T12PR48 (eRVR+)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 36 weeks of Peg-IFN-alfa-2a and RBV; subjects achieved an extended rapid viral response (eRVR+) and were randomized to this group
T12PR48 (eRVR-)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 36 weeks of Peg-IFN-alfa-2a and RBV; subjects did not achieve an extended rapid viral response (eRVR-) and were assigned to this group
Other	Subjects who received at least 1 dose of study drug, but prematurely discontinued treatment before Week 20 were not randomized or assigned to a treatment regimen.

Overall Study

	T12PR24 (eRVR+)	T12PR48 (eRVR+)	T12PR48 (eRVR-)	Other
Started	162	160	118	100
Completed	161	119	79	0
Not Completed	1	41	39	100
Adverse Event	1	20	12	62
Lack of Efficacy	0	6	18	12

	T12PR24 (eRVR+)	T12PR48 (eRVR+)	T12PR48 (eRVR-)	Other
Refused Further Treatment	0	11	5	8
Lost to Follow-up	0	2	2	5
Withdrawal by Subject	0	1	1	4
Required Prohibited Medication	0	0	1	3
Non-Compliant With study Drug	0	0	0	1
Other Reasons	0	1	0	5

Baseline Characteristics

Reporting Groups

	Description
T12PR24 (eRVR+)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 12 weeks of Peg-IFN-alfa-2a and RBV; subjects achieved an extended rapid viral response (eRVR+) and were randomized to this group
T12PR48 (eRVR+)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 36 weeks of Peg-IFN-alfa-2a and RBV; subjects achieved an extended rapid viral response (eRVR+) and were randomized to this group
T12PR48 (eRVR-)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 36 weeks of Peg-IFN-alfa-2a and RBV; subjects did not achieve an extended rapid viral response (eRVR-) and were assigned to this group
Other	Subjects who received at least 1 dose of study drug, but prematurely discontinued treatment before Week 20 were not randomized or assigned to a treatment regimen.

Baseline Measures

	T12PR24 (eRVR+)	T12PR48 (eRVR+)	T12PR48 (eRVR-)	Other	Total
Overall Number of Participants	162	160	118	100	540

		T12PR24 (eRVR+)	T12PR48 (eRVR+)	T12PR48 (eRVR-)	Other	Total
Age, Categorical Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	162 participants	160 participants	118 participants	100 participants	540 participants
	<=18 years	0 0%	0 0%	0 0%	0 0%	0 0%
	Between 18 and 65 years	158 97.53%	157 98.12%	118 100%	99 99%	532 98.52%
	>=65 years	4 2.47%	3 1.88%	0 0%	1 1%	8 1.48%
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	162 participants	160 participants	118 participants	100 participants	540 participants
		48.6 (8.9)	48.3 (9.9)	49.5 (8.7)	51.6 (8.4)	49.3 (9.2)
Gender, Male/ Female Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	162 participants	160 participants	118 participants	100 participants	540 participants
	Female	58 35.8%	63 39.38%	48 40.68%	46 46%	215 39.81%
	Male	104 64.2%	97 60.62%	70 59.32%	54 54%	325 60.19%
Region of Enrollment Measure Type: Number Unit of measure: participants	Number Analyzed	162 participants	160 participants	118 participants	100 participants	540 participants
North America		154	151	106	98	509
Europe		8	9	12	2	31

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Proportion of Randomized Subjects Achieving Sustained Viral Response (SVR), Demonstrated by Achieving Undetectable HCV RNA 24 Weeks After Last Dose of Study Treatment (SVR24)
Measure Description	SVR24planned was used to measure the primary outcome. SVR24 planned is defined as undetectable HCV RNA levels at the end of treatment (EOT) visit and at 24 weeks after the last planned dose of study treatment without any confirmed detectable HCV RNA levels in between those visits. All plasma HCV RNA levels were assessed using the Roche TaqMan HCV RNA assay (Version 2.0, lower limit of quantification [LLOQ] of 25 IU/mL).

Time Frame	24 weeks after the last planned dose of study treatment
Safety Issue?	No

Analysis Population Description

The population analyzed included all subjects in the Full Analysis (FA) Set. All subjects in the FA Set received at least 1 dose of study drug.

Reporting Groups

	Description
T12PR24 (eRVR+)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 12 weeks of Peg-IFN-alfa-2a and RBV; subjects achieved an extended rapid viral response (eRVR+) and were randomized to this group
T12PR48 (eRVR+)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 36 weeks of Peg-IFN-alfa-2a and RBV; subjects achieved an extended rapid viral response (eRVR+) and were randomized to this group
T12PR48 (eRVR-)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 36 weeks of Peg-IFN-alfa-2a and RBV; subjects did not achieve an extended rapid viral response (eRVR-) and were assigned to this group
Other	Subjects who received at least 1 dose of study drug, but prematurely discontinued treatment before Week 20 were not randomized or assigned to a treatment regimen.

Measured Values

	T12PR24 (eRVR+)	T12PR48 (eRVR+)	T12PR48 (eRVR-)	Other
Number of Participants Analyzed	162	160	118	100
Proportion of Randomized Subjects Achieving Sustained Viral Response (SVR), Demonstrated by Achieving Undetectable HCV RNA 24 Weeks After Last Dose of Study Treatment (SVR24) Measure Type: Number Unit of measure: participants				
SVR24 (Statistical Analysis 1)	149	140	76	23
SVR24 (Statistical Analysis 2)	149	144	78	27

Statistical Analysis 1 for Proportion of Randomized Subjects Achieving Sustained Viral Response (SVR), Demonstrated by Achieving Undetectable HCV RNA 24 Weeks After Last Dose of Study Treatment (SVR24)

Statistical Analysis Overview	Comparison Groups	T12PR24 (eRVR+), T12PR48 (eRVR+)

	Comments	Primary efficacy analysis was based on CI estimates (using the normal approximation, confidence limits were constructed for the difference in proportions) to rule out the inferiority of the T12/PR24/eRVR+ treatment regimen relative to the T12/PR48/eRVR+ treatment regimen. SVR24 was defined as undetectable HCV RNA at end of treatment through 24 weeks after the last planned dose.
	Non-Inferiority or Equivalence Analysis?	Yes
	Comments	Estimated by evaluating the treatment differences in the SVR24planned rates (T12PR24/ eRVR+ minus T12PR48/eRVR+) and the 95% CI for these groups (the entire 2 sided CI is to the right of the predefined non-inferiority margin of -10.5%).

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]
	Method	Other [Confidence Interval]
	Comments	Treatment difference is estimated by the confidence interval.

Method of Estimation	Estimation Parameter	Other [Difference in proportions]
	Estimated Value	4.5
	Confidence Interval	(2-Sided) 95% -2.1 to 11.1
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Proportion of Randomized Subjects Achieving Sustained Viral Response (SVR), Demonstrated by Achieving Undetectable HCV RNA 24 Weeks After Last Dose of Study Treatment (SVR24)

Statistical Analysis Overview	Comparison Groups	T12PR24 (eRVR+), T12PR48 (eRVR+)
	Comments	SVR24 was defined as below the limit of quantitation at 24 weeks after the planned end of treatment. For subjects who had missing data at week 24 after the planned end of treatment, the week 12 data or the last follow-up time point after week 12 was carried forward for determining SVR24.
	Non-Inferiority or Equivalence Analysis?	Yes
	Comments	Estimated by evaluating the treatment differences in the SVR24planned rates (T12PR24/ eRVR+ minus T12PR48/eRVR+) and the 95% CI for these groups (the entire 2 sided CI is to the right of the predefined non-inferiority margin of -10.5%).

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]

	Method	Other [Confidence Interval]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in proportions]
	Estimated Value	2.0
	Confidence Interval	(2-Sided) 95% -4.3 to 8.2
	Estimation Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Proportion of Subjects Who Have Undetectable HCV RNA at Week 72
Measure Description	SVR at Week 72 is defined as achieved SVR24planned and undetectable HCV RNA at Week 72 without any confirmed detectable HCV RNA levels in between those visits.
Time Frame	72 weeks after the last planned dose of study treatment
Safety Issue?	No

Analysis Population Description

The population analyzed included all subjects in the Full Analysis (FA) Set. All subjects in the FA Set received at least 1 dose of study drug.

Reporting Groups

	Description
T12PR24 (eRVR+)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 12 weeks of Peg-IFN-alfa-2a and RBV; subjects achieved an extended rapid viral response and were randomized to this group
T12PR48 (eRVR+)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 36 weeks of Peg-IFN-alfa-2a and RBV; subjects achieved an extended rapid viral response and were randomized to this group
T12PR48 (eRVR-)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 36 weeks of Peg-IFN-alfa-2a and RBV; subjects did not achieve an extended rapid viral response and were assigned to this group (not randomized)
Other	Subjects who received at least 1 dose of study drug, but prematurely discontinued treatment before Week 20, were not randomized or assigned to a treatment regimen

Measured Values

	T12PR24 (eRVR+)	T12PR48 (eRVR+)	T12PR48 (eRVR-)	Other
Number of Participants Analyzed	162	160	118	100

	T12PR24 (eRVR+)	T12PR48 (eRVR+)	T12PR48 (eRVR-)	Other
Proportion of Subjects Who Have Undetectable HCV RNA at Week 72 Measure Type: Number Unit of measure: participants	141	140	76	20

Statistical Analysis 1 for Proportion of Subjects Who Have Undetectable HCV RNA at Week 72

Statistical Analysis Overview	Comparison Groups	T12PR24 (eRVR+), T12PR48 (eRVR+)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	Yes
	Comments	Estimated by evaluating the treatment differences in the SVR at Week 72 planned rates (T12PR24/eRVR+ minus T12PR48/eRVR+) and the 95% CI for these groups (the entire 2 sided CI is to the right of the predefined non-inferiority margin of 10.5%).

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]
	Method	Regression, Logistic
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in Proportion]
	Estimated Value	-0.5
	Confidence Interval	(2-Sided) 95% -7.7 to 6.8
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Proportion of Subjects Who Have Undetectable HCV RNA at Week 72

Statistical Analysis Overview	Comparison Groups	T12PR24 (eRVR+), T12PR48 (eRVR+)
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	Yes
	Comments	Estimated by evaluating the treatment differences in the SVR at Week 72 planned rates (T12PR24/eRVR+ minus T12PR48/eRVR+) and the 95% CI for these groups (the entire 2 sided CI is to the right of the predefined non-inferiority margin of 10.5%).

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]
	Method	Regression, Logistic
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Odds Ratio, log
	Estimated Value	0.94
	Confidence Interval	(2-Sided) 95% 0.49 to 1.82
	Estimation Comments	[Not specified]

3. Secondary Outcome Measure:

Measure Title	Proportion of Subjects Achieving eRVR (Extended RVR), Demonstrated by Achieving Undetectable HCV RNA at Week 4 and at Week 12
Measure Description	Extended rapid viral response is defined undetectable HCV RNA levels at Week 4 and Week 12 (on treatment).
Time Frame	Week 4 and Week 12
Safety Issue?	No

Analysis Population Description

The population analyzed included all subjects in the Full Analysis (FA) Set. All subjects in the FA Set received at least 1 dose of study drug.

Reporting Groups

	Description
T12PR24 (eRVR+)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 12 weeks of Peg-IFN-alfa-2a and RBV; subjects achieved an extended rapid viral response and were randomized to this group
T12PR48 (eRVR+)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 36 weeks of Peg-IFN-alfa-2a and RBV; subjects achieved an extended rapid viral response and were randomized to this group
T12PR48 (eRVR-)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 36 weeks of Peg-IFN-alfa-2a and RBV; subjects did not achieve an extended rapid viral response and were assigned to this group (not randomized)
Other	Subjects who received at least 1 dose of study drug, but prematurely discontinued treatment before Week 20, were not randomized or assigned to a treatment regimen

Measured Values

	T12PR24 (eRVR+)	T12PR48 (eRVR+)	T12PR48 (eRVR-)	Other
Number of Participants Analyzed	162	160	118	100
Proportion of Subjects Achieving eRVR (Extended RVR), Demonstrated by Achieving Undetectable HCV RNA at Week 4 and at Week 12 Measure Type: Number Unit of measure: participants	162	159	0	31

4. Secondary Outcome Measure:

Measure Title	Proportion of Randomized Subjects Who Have Undetectable HCV RNA 12 Weeks After Last Dose of Study Treatment
Measure Description	SVR12 is defined as undetectable HCV RNA levels 12 weeks after the last planned dose of study treatment.
Time Frame	12 weeks after last dose of study treatment
Safety Issue?	No

Analysis Population Description

The population analyzed included all subjects in the Full Analysis (FA) Set. All subjects in the FA Set received at least 1 dose of study drug.

Reporting Groups

	Description
T12PR24 (eRVR+)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 12 weeks of Peg-IFN-alfa-2a and RBV; subjects achieved an extended rapid viral response (eRVR+) and were randomized to this group
T12PR48 (eRVR+)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 36 weeks of Peg-IFN-alfa-2a and RBV; subjects achieved an extended rapid viral response (eRVR+) and were randomized to this group
T12PR48 (eRVR-)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 36 weeks of Peg-IFN-alfa-2a and RBV; subjects did not achieve an extended rapid viral response (eRVR-) and were assigned to this group
Other	Subjects who received at least 1 dose of study drug, but prematurely discontinued treatment before Week 20 were not randomized or assigned to a treatment regimen.

Measured Values

	T12PR24 (eRVR+)	T12PR48 (eRVR+)	T12PR48 (eRVR-)	Other
Number of Participants Analyzed	162	160	118	100

	T12PR24 (eRVR+)	T12PR48 (eRVR+)	T12PR48 (eRVR-)	Other
Proportion of Randomized Subjects Who Have Undetectable HCV RNA 12 Weeks After Last Dose of Study Treatment Measure Type: Number Unit of measure: participants	151	144	79	28

5. Secondary Outcome Measure:

Measure Title	Proportion of Subjects Who Have Undetectable HCV RNA at the EOT (Week 24 or Week 48 Respectively).
Measure Description	
Time Frame	Week 24 or Week 48
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
T12PR24 (eRVR+)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 12 weeks of Peg-IFN-alfa-2a and RBV; subjects achieved an extended rapid viral response and were randomized to this group
T12PR48 (eRVR+)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 36 weeks of Peg-IFN-alfa-2a and RBV; subjects achieved an extended rapid viral response and were randomized to this group
T12PR48 (eRVR-)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 36 weeks of Peg-IFN-alfa-2a and RBV; subjects did not achieve an extended rapid viral response and were assigned to this group (not randomized)
Other	Subjects who received at least 1 dose of study drug, but prematurely discontinued treatment before Week 20, were not randomized or assigned to a treatment regimen

Measured Values

	T12PR24 (eRVR+)	T12PR48 (eRVR+)	T12PR48 (eRVR-)	Other
Number of Participants Analyzed	162	160	118	100
Proportion of Subjects Who Have Undetectable HCV RNA at the EOT (Week 24 or Week 48 Respectively). Measure Type: Number Unit of measure: participants	159	154	97	59

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

	Description
T12PR24 (eRVR+)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 12 weeks of Peg-IFN-alfa-2a and RBV; subjects achieved an extended rapid viral response (eRVR+) and were randomized to this group
T12PR48 (eRVR+)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 36 weeks of Peg-IFN-alfa-2a and RBV; subjects achieved an extended rapid viral response (eRVR+) and were randomized to this group
T12PR48 (eRVR-)	Telaprevir + Peg-IFN-alfa-2a + RBV for 12 weeks, followed by 36 weeks of Peg-IFN-alfa-2a and RBV; subjects did not achieve an extended rapid viral response (eRVR-) and were assigned to this group
Other	Subjects who received at least 1 dose of study drug, but prematurely discontinued treatment before Week 20 were not randomized or assigned to a treatment regimen.

Serious Adverse Events

	T12PR24 (eRVR+)	T12PR48 (eRVR+)	T12PR48 (eRVR-)	Other
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	4/162 (2.47%)	16/160 (10%)	7/118 (5.93%)	22/100 (22%)

Other Adverse Events

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

	T12PR24 (eRVR+)	T12PR48 (eRVR+)	T12PR48 (eRVR-)	Other
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	161/162 (99.38%)	160/160 (100%)	117/118 (99.15%)	99/100 (99%)

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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