ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: July 16, 2014

ClinicalTrials.gov ID: NCT00627926

Study Identification

Unique Protocol ID: VX07-950-108

Brief Title: A Phase 3 Study of Telaprevir in Combination With Pegasys® and Copegus® in Treatment-Naive Subjects With Genotype 1 Hepatitis C Virus (HCV)

Official Title: A Phase 3 Study of 2 Dose Regimens of Telaprevir in Combination With Peginterferon Alfa-2a (Pegasys®) and Ribavirin (Copegus®) in Treatment-Naive Subjects With Genotype 1 Chronic Hepatitis C

Secondary IDs:

Study Status

Record Verification: July 2014

Overall Status: Completed

Study Start: March 2008

Primary Completion: May 2010 [Actual]

Study Completion: May 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: 71832 Serial Number: 0173 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

Study Description

Brief Summary:	A Phase 3 study to evaluate the efficacy and safety of two dosing regimens of telaprevir in combination with pegylated interferon alfa 2a (Peg-IFN-alfa-2a) and ribavirin (RBV).
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:	3
Masking:	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)

Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	1095 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Placebo Comparator: PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week Placebo (PBO) matched to 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 48 weeks.	Biological/Vaccine: Pegylated Interferon Alfa 2a subcutaneous injection, 180 micrograms once per week Other Names: • Pegasys, Peg-IFN-alfa-2a Drug: Ribavirin 200 mg tablets administered orally twice daily at a dose of 1000 mg/day for subjects weighing <75 kg and 1200 mg/day for subjects weighing ≥75 kg Other Names: • Copegus, RBV Placebo Telaprevir matching placebo
Experimental: Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week Telaprevir 750 mg tablet thrice daily for 8 weeks, then PBO matched to Telaprevir 750 mg tablet thrice daily for 4 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 24 to 48 weeks depending on individual response to telaprevir treatment.	Biological/Vaccine: Pegylated Interferon Alfa 2a subcutaneous injection, 180 micrograms once per week Other Names: • Pegasys, Peg-IFN-alfa-2a Drug: Telaprevir 375 mg tablets administered orally every 8 hours at a dose of 750 mg Other Names: • VX-950 Drug: Ribavirin 200 mg tablets administered orally twice daily at a dose of 1000 mg/day for subjects weighing <75 kg and 1200 mg/day for subjects weighing ≥75 kg Other Names: • Copegus, RBV Placebo Telaprevir matching placebo
Experimental: Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 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	Biological/Vaccine: Pegylated Interferon Alfa 2a subcutaneous injection, 180 micrograms once per week Other Names:

Arms	Assigned Interventions
twice daily at a dose of 1000 mg/day for subjects weighing <75 kg and 1200 mg/day for subjects weighing >=75 kg, for 24 to 48 weeks depending on individual response to telaprevir treatment.	• Pegasys, Peg-IFN-alfa-2a Drug: Telaprevir 375 mg tablets administered orally every 8 hours at a dose of 750 mg Other Names: • VX-950 Drug: Ribavirin 200 mg tablets administered orally twice daily at a dose of 1000 mg/day for subjects weighing <75 kg and 1200 mg/day for subjects weighing ≥75 kg Other Names: • Copegus, RBV

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 Hepatitis C Virus (HCV) Ribonucleic Acid (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: Medical Monitor
Study Director
Vertex Pharmaceuticals Incorporated

Locations: United States, Texas
San Antonio, Texas, United States, 78215

Puerto Rico
Santurce, Puerto Rico, 00909

United States, Alabama
Birmingham, Alabama, United States, 35209

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

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

United States, Georgia
Atlanta, Georgia, United States, 30308

United States, North Carolina
Fayetteville, North Carolina, United States, 28304

United States, Maryland
Laurel, Maryland, United States, 20707

United States, California
San Diego, California, United States, 92123

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

United States, Florida
Jacksonville, Florida, United States, 32256

Orlando, Florida, United States, 32803

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

United States, New Mexico

Albuquerque, New Mexico, United States, 87131

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

United States, Indiana
Carmel, Indiana, United States, 46032

United States, California
LaJolla, California, United States, 92037

United States, New York
New York City, New York, United States, 10032

United States, Texas
Dallas, Texas, United States, 75203

United States, Florida
Sarasota, Florida, United States, 34243

United States, Ohio
Cincinnati, Ohio, United States, 45219

Cincinatti, Ohio, United States, 45267

United States, Virginia
Annandale, Virginia, United States, 22003

United States, Colorado
Aurora, Colorado, United States, 80045

United States, Alabama
Birmingham, Alabama, United States, 35294

United States, Massachusetts
Boston, Massachusetts, United States, 02114

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

Charlotte, North Carolina, United States, 28203

United States, Virginia
Charlottesville, Virginia, United States, 22908

United States, Illinois

Chicago, Illinois, United States, 60637

United States, Ohio
Cleveland, Ohio, United States, 44195

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

Dallas, Texas, United States, 75390

United States, North Carolina
Durham, North Carolina, United States, 27710

United States, Virginia
Richmond, Virginia, United States, 23249

United States, California
Fresno, California, United States, 93721

United States, Florida
Gainesville, Florida, United States, 32610

United States, Pennsylvania
Hershey, Pennsylvania, United States, 17033

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

United States, Texas
Houston, Texas, United States, 77030

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

United States, Florida
Jacksonville, Florida, United States, 32224

United States, California
Long Beach, California, United States, 90822

Los Angeles, California, United States, 90033

Los Angeles, California, United States, 90048

United States, New York
Manhasset, New York, United States, 11030

United States, Florida
Miami, Florida, United States, 33136

United States, New York
New York City, New York, United States, 10029

New York City, New York, United States, 10003

New York City, New York, United States, 10021

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

United States, Nebraska
Omaha, Nebraska, United States, 68105

United States, Pennsylvania
Philadelphia, Pennsylvania, United States, 19104

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

United States, Pennsylvania
Pittsburgh, Pennsylvania, United States, 15213

United States, Maine
Portland, Maine, United States, 04102

United States, California
San Diego, California, United States, 92154

San Diego, California, United States, 92103

San Francisco, California, United States, 94115

San Francisco, California, United States, 94121

San Francisco, California, United States, 94143

United States, Georgia
Savannah, Georgia, United States, 31405

United States, Florida
South Miami, Florida, United States, 33143

United States, Missouri
St Louis, Missouri, United States, 63104

United States, New York
Valhalla, New York, United States, 10595

United States, Massachusetts
Worcester, Massachusetts, United States, 01655

Argentina
Buenos Aires, Argentina

Australia
Perth, Australia

Greenslopes, Australia

Fitzroy, Australia

Darlinghurst, Australia

Westmead, Australia

Woolloongabba, Australia

Melbourne, Australia

Austria
Vienna, Austria

Linz, Austria

France
Pessac, France

Clichy, France

Creteil, France

Paris, France

Nice, France

Grenoble, France

Toulouse, France

Lyon, France

Germany

- Berlin, Germany
- Hamburg, Germany
- Muenchen, Germany
- Koln, Germany
- Freiburg, Germany
- Bochum, Germany
- Hannover, Germany
- Frankfurt, Germany
- Dusseldorf, Germany

Israel
- Tel Hashomer, Israel
- Haifa, Israel
- Petah Tikva, Israel
- Nazareth, Israel
- Jerusalem, Israel

Poland
- Krakow, Poland
- Bialystok, Poland
- Wroclaw, Poland
- Czeladz, Poland
- Kielce, Poland
- Lodz, Poland

Spain
- Barcelona, Spain
- Valencia, Spain

Canada
- Toronto, Canada
- Winnipeg, Canada
- Calgary, Canada
- Vancouver, Canada

United Kingdom
- London, United Kingdom
- Glasgow, United Kingdom
- Hampstead, United Kingdom

Argentina
- Buenos Aires, Argentina

Austria
- Vienna, Austria
- Vienna, Austria

Canada
- Toronto, Canada

France
- Paris, France

Israel
- Haifa, Israel

Italy
- Milano, Italy
- Torino, Italy
- Bologna, Italy

Spain
- Barcelona, Spain
- Barcelona, Spain

United Kingdom

London, United Kingdom

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Pre-Assignment Details	A total of 1095 subjects were enrolled, of which 7 subjects discontinued the study prior to study drug administration. A total of 1088 subjects started treatment.

Reporting Groups

	Description
PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Placebo (PBO) matched to 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 48 weeks.
Telaprevir 8 Week, PBO 4 Week +Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 750 mg tablet thrice daily for 8 weeks, then PBO matched to Telaprevir 750 mg tablet thrice daily for 4 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 24 to 48 weeks depending on individual response to telaprevir treatment.
Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 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 24 to 48 weeks depending on individual response to telaprevir treatment.

Overall Study

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week +Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
Started	361	364	363
Completed	202	260	268

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week +Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
Not Completed	159	104	95
Adverse Event	26	37	36
Death	1	0	0
Lost to Follow-up	4	3	4
Withdrawal by Subject	2	1	0
Lack of Efficacy	118	40	38
Noncompliance/ unspecified	8	23	17

Baseline Characteristics

Baseline Analysis Population Description

The full analysis (FA) set included all randomized subjects who received at least 1 dose of any study drug.

Reporting Groups

	Description
PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Placebo (PBO) matched to 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 48 weeks.
Telaprevir 8 Week, PBO 4 Week +Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 750 mg tablet thrice daily for 8 weeks, then PBO matched to Telaprevir 750 mg tablet thrice daily for 4 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 24 to 48 weeks depending on individual response to telaprevir treatment.
Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 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 24 to 48 weeks depending on individual response to telaprevir treatment.

Baseline Measures

		PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Total
Overall Number of Participants		361	364	363	1088
Age, Categorical Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	361 participants	364 participants	363 participants	1088 participants
	<=18 years	1 0.28%	0 0%	0 0%	1 0.09%
	Between 18 and 65 years	357 98.89%	359 98.63%	353 97.25%	1069 98.25%
	>=65 years	3 0.83%	5 1.37%	10 2.75%	18 1.65%
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	361 participants	364 participants	363 participants	1088 participants
		46.8 (10.0)	47.0 (10.9)	46.5 (10.8)	46.8 (10.6)
Gender, Male/Female Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	361 participants	364 participants	363 participants	1088 participants
	Female	150 41.55%	153 42.03%	149 41.05%	452 41.54%
	Male	211 58.45%	211 57.97%	214 58.95%	636 58.46%
Region of Enrollment Measure Type: Number Unit of measure: participants	Number Analyzed	361 participants	364 participants	363 participants	1088 participants
North America		214	227	214	655
Europe		106	100	104	310
Argentina		8	6	3	17
Australia		14	14	18	46
Israel		19	17	24	60

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Subjects Achieving Sustained Viral Response (SVR), Demonstrated by Achieving Undetectable Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Levels 24 Weeks After Last Planned Dose of Study Treatment
Measure Description	The plasma HCV RNA level was measured using Roche TaqMan HCV RNA assay. The lower limit of quantification was 25 international units per milliliter (IU/mL) and the lower limit of detection was 10 IU/mL. Two results are reported: 1) Protocol defined SVR: undetectable HCV RNA at 24 weeks after the last planned dose of study treatment without any confirmed detectable HCV RNA between end of treatment visit (up to Week 48) and 24 weeks after last planned dose (up to Week 72); 2) SVR as per FDA guidance (snapshot analysis): undetectable HCV RNA at 24 weeks after the last planned dose of study treatment. Analysis was based only on the HCV RNA assessment in visit window (+/-2 weeks); if there were more than 1 assessment in the window, the last measurement was used.
Time Frame	24 weeks after last planned dose of study treatment (up to Week 72)
Safety Issue?	No

Analysis Population Description

The full analysis (FA) set included all randomized subjects who received at least 1 dose of any study drug.

Reporting Groups

	Description
PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Placebo (PBO) matched to 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 48 weeks.
Telaprevir 8 Week, PBO 4 Week +Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 750 mg tablet thrice daily for 8 weeks, then PBO matched to Telaprevir 750 mg tablet thrice daily for 4 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 24 to 48 weeks depending on individual response to telaprevir treatment.
Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 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 24 to 48 weeks depending on individual response to telaprevir treatment.

Measured Values

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
Number of Participants Analyzed	361	364	363

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
Number of Subjects Achieving Sustained Viral Response (SVR), Demonstrated by Achieving Undetectable Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Levels 24 Weeks After Last Planned Dose of Study Treatment Measure Type: Number Unit of measure: participants			
SVR: Protocol Defined	158	250	271
SVR: FDA Guidance	166	261	285

Statistical Analysis 1 for Number of Subjects Achieving Sustained Viral Response (SVR), Demonstrated by Achieving Undetectable Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Levels 24 Weeks After Last Planned Dose of Study Treatment

Statistical Analysis Overview	Comparison Groups	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week, Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
	Comments	SVR Protocol Defined: undetectable HCV RNA at 24 weeks after the last planned dose of study treatment without any confirmed detectable HCV RNA between end of treatment visit (up to Week 48) and 24 weeks after last planned dose (up to Week 72).
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in percentage]
	Estimated Value	24.9
	Confidence Interval	(2-Sided) 95% 17.9 to 31.9
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Number of Subjects Achieving Sustained Viral Response (SVR), Demonstrated by Achieving Undetectable Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Levels 24 Weeks After Last Planned Dose of Study Treatment

Statistical Analysis Overview	Comparison Groups	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week, Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week

	Comments	SVR Protocol Defined: undetectable HCV RNA at 24 weeks after the last planned dose of study treatment without any confirmed detectable HCV RNA between end of treatment visit (up to Week 48) and 24 weeks after last planned dose (up to Week 72).
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in percentage]
	Estimated Value	30.9
	Confidence Interval	(2-Sided) 95% 24.1 to 37.7
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Number of Subjects Achieving Sustained Viral Response (SVR), Demonstrated by Achieving Undetectable Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Levels 24 Weeks After Last Planned Dose of Study Treatment

Statistical Analysis Overview	Comparison Groups	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week, Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
	Comments	SVR FDA Guidance: undetectable HCV RNA at 24 weeks after the last planned dose of study treatment. Analysis was based only on the HCV RNA assessment in visit window (+/-2 weeks); if there were more than 1 assessment in the window, the last measurement was used.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in percentage]
	Estimated Value	25.7
	Confidence Interval	(2-Sided) 95% 18.8 to 32.6
	Estimation Comments	[Not specified]

Statistical Analysis 4 for Number of Subjects Achieving Sustained Viral Response (SVR), Demonstrated by Achieving Undetectable Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Levels 24 Weeks After Last Planned Dose of Study Treatment

Statistical Analysis Overview	Comparison Groups	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week, Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week

	Comments	SVR FDA Guidance: undetectable HCV RNA at 24 weeks after the last planned dose of study treatment. Analysis was based only on the HCV RNA assessment in visit window (+/-2 weeks); if there were more than 1 assessment in the window, the last measurement was used.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in percentage]
	Estimated Value	32.5
	Confidence Interval	(2-Sided) 95% 25.9 to 39.2
	Estimation Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Number of Subjects With Undetectable HCV RNA at Week 72
Measure Description	The plasma HCV RNA level was measured using Roche TaqMan HCV RNA assay. The lower limit of quantification was 25 IU/mL and the lower limit of detection was 10 IU/mL.
Time Frame	Week 72 (24 weeks after last dose for subjects with a planned treatment duration of 48 weeks and 48 weeks after last dose for subjects with planned treatment duration of 24 weeks)
Safety Issue?	No

Analysis Population Description

The FA set included all randomized subjects who received at least 1 dose of any study drug.

Reporting Groups

	Description
PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Placebo (PBO) matched to 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 48 weeks.
Telaprevir 8 Week, PBO 4 Week +Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 750 mg tablet thrice daily for 8 weeks, then PBO matched to Telaprevir 750 mg tablet thrice daily for 4 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 24 to 48 weeks depending on individual response to telaprevir treatment.

	Description
Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 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 24 to 48 weeks depending on individual response to telaprevir treatment.

Measured Values

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
Number of Participants Analyzed	361	364	363
Number of Subjects With Undetectable HCV RNA at Week 72 Measure Type: Number Unit of measure: participants	158	243	265

Statistical Analysis 1 for Number of Subjects With Undetectable HCV RNA at Week 72

Statistical Analysis Overview	Comparison Groups	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week, Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in percentage]
	Estimated Value	23.0
	Confidence Interval	(2-Sided) 95% 15.9 to 30.0
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Number of Subjects With Undetectable HCV RNA at Week 72

Statistical Analysis Overview	Comparison Groups	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week, Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
	Comments	[Not specified]

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in percentage]
	Estimated Value	29.2
	Confidence Interval	(2-Sided) 95% 22.4 to 36.1
	Estimation Comments	[Not specified]

3. Secondary Outcome Measure:

Measure Title	Number of Subjects Achieving Rapid Viral Response (RVR), Demonstrated by Achieving Undetectable HCV RNA 4 Weeks After Starting Study Treatment
Measure Description	The plasma HCV RNA level was measured using Roche TaqMan HCV RNA assay. The lower limit of quantification was 25 IU/mL and the lower limit of detection was 10 IU/mL. RVR was defined as undetectable HCV RNA 4 weeks after the start of study treatment.
Time Frame	Week 4
Safety Issue?	No

Analysis Population Description

The FA set included all randomized subjects who received at least 1 dose of any study drug.

Reporting Groups

	Description
PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Placebo (PBO) matched to 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 48 weeks.
Telaprevir 8 Week, PBO 4 Week +Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 750 mg tablet thrice daily for 8 weeks, then PBO matched to Telaprevir 750 mg tablet thrice daily for 4 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 24 to 48 weeks depending on individual response to telaprevir treatment.
Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 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 24 to 48 weeks depending on individual response to telaprevir treatment.

Measured Values

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
Number of Participants Analyzed	361	364	363
Number of Subjects Achieving Rapid Viral Response (RVR), Demonstrated by Achieving Undetectable HCV RNA 4 Weeks After Starting Study Treatment Measure Type: Number Unit of measure: participants	34	242	246

Statistical Analysis 1 for Number of Subjects Achieving Rapid Viral Response (RVR), Demonstrated by Achieving Undetectable HCV RNA 4 Weeks After Starting Study Treatment

Statistical Analysis Overview	Comparison Groups	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week, Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in percentage]
	Estimated Value	57.1
	Confidence Interval	(2-Sided) 95% 51.4 to 62.8
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Number of Subjects Achieving Rapid Viral Response (RVR), Demonstrated by Achieving Undetectable HCV RNA 4 Weeks After Starting Study Treatment

Statistical Analysis Overview	Comparison Groups	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week, Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in percentage]
	Estimated Value	58.4
	Confidence Interval	(2-Sided) 95% 52.7 to 64.0
	Estimation Comments	[Not specified]

4. Secondary Outcome Measure:

Measure Title	Number of Subjects Achieving Extended Rapid Viral Response (eRVR), Demonstrated by Achieving Undetectable HCV RNA at Week 4 and at Week 12
Measure Description	The plasma HCV RNA level was measured using Roche TaqMan HCV RNA assay. The lower limit of quantification was 25 IU/mL and the lower limit of detection was 10 IU/mL. eRVR was defined as undetectable HCV RNA at both Week 4 and Week 12.
Time Frame	Week 4 and Week 12
Safety Issue?	No

Analysis Population Description

The FA set included all randomized subjects who received at least 1 dose of any study drug.

Reporting Groups

	Description
PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Placebo (PBO) matched to 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 48 weeks.
Telaprevir 8 Week, PBO 4 Week +Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 750 mg tablet thrice daily for 8 weeks, then PBO matched to Telaprevir 750 mg tablet thrice daily for 4 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 24 to 48 weeks depending on individual response to telaprevir treatment.
Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 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 24 to 48 weeks depending on individual response to telaprevir treatment.

Measured Values

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
Number of Participants Analyzed	361	364	363
Number of Subjects Achieving Extended Rapid Viral Response (eRVR), Demonstrated by Achieving Undetectable HCV RNA at Week 4 and at Week 12 Measure Type: Number Unit of measure: participants	29	207	212

Statistical Analysis 1 for Number of Subjects Achieving Extended Rapid Viral Response (eRVR), Demonstrated by Achieving Undetectable HCV RNA at Week 4 and at Week 12

Statistical Analysis Overview	Comparison Groups	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week, Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in percentage]
	Estimated Value	48.8
	Confidence Interval	(2-Sided) 95% 43.0 to 54.6
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Number of Subjects Achieving Extended Rapid Viral Response (eRVR), Demonstrated by Achieving Undetectable HCV RNA at Week 4 and at Week 12

Statistical Analysis Overview	Comparison Groups	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week, Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in percentage]
	Estimated Value	50.4
	Confidence Interval	(2-Sided) 95% 44.6 to 56.2
	Estimation Comments	[Not specified]

5. Secondary Outcome Measure:

Measure Title	Number of Subjects With Undetectable HCV RNA at Week 12
Measure Description	The plasma HCV RNA level was measured using Roche TaqMan HCV RNA assay. The lower limit of quantification was 25 IU/mL and the lower limit of detection was 10 IU/mL.
Time Frame	Week 12
Safety Issue?	No

Analysis Population Description

The FA set included all randomized subjects who received at least 1 dose of any study drug.

Reporting Groups

	Description
PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Placebo (PBO) matched to 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 48 weeks.
Telaprevir 8 Week, PBO 4 Week +Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 750 mg tablet thrice daily for 8 weeks, then PBO matched to Telaprevir 750 mg tablet thrice daily for 4 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 24 to 48 weeks depending on individual response to telaprevir treatment.
Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 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 24 to 48 weeks depending on individual response to telaprevir treatment.

Measured Values

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
Number of Participants Analyzed	361	364	363

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
Number of Subjects With Undetectable HCV RNA at Week 12 Measure Type: Number Unit of measure: participants	146	277	283

Statistical Analysis 1 for Number of Subjects With Undetectable HCV RNA at Week 12

Statistical Analysis Overview	Comparison Groups	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week, Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in percentage]
	Estimated Value	35.7
	Confidence Interval	(2-Sided) 95% 29.0 to 42.4
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Number of Subjects With Undetectable HCV RNA at Week 12

Statistical Analysis Overview	Comparison Groups	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week, Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in percentage]
	Estimated Value	37.5
	Confidence Interval	(2-Sided) 95% 30.9 to 44.1

	Estimation Comments	[Not specified]

6. Secondary Outcome Measure:

Measure Title	Number of Subjects With Undetectable HCV RNA at End of Treatment (EOT)
Measure Description	The plasma HCV RNA level was measured using Roche TaqMan HCV RNA assay. The lower limit of quantification was 25 IU/mL and the lower limit of detection was 10 IU/mL.
Time Frame	End of treatment (up to Week 48)
Safety Issue?	No

Analysis Population Description

The FA set included all randomized subjects who received at least 1 dose of any study drug.

Reporting Groups

	Description
PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Placebo (PBO) matched to 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 48 weeks.
Telaprevir 8 Week, PBO 4 Week +Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 750 mg tablet thrice daily for 8 weeks, then PBO matched to Telaprevir 750 mg tablet thrice daily for 4 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 24 to 48 weeks depending on individual response to telaprevir treatment.
Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 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 24 to 48 weeks depending on individual response to telaprevir treatment.

Measured Values

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
Number of Participants Analyzed	361	364	363
Number of Subjects With Undetectable HCV RNA at End of Treatment (EOT) Measure Type: Number Unit of measure: participants	229	295	314

Statistical Analysis 1 for Number of Subjects With Undetectable HCV RNA at End of Treatment (EOT)

Statistical Analysis Overview	Comparison Groups	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week, Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in percentage]
	Estimated Value	17.6
	Confidence Interval	(2-Sided) 95% 11.2 to 24.0
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Number of Subjects With Undetectable HCV RNA at End of Treatment (EOT)

Statistical Analysis Overview	Comparison Groups	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week, Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in percentage]
	Estimated Value	23.1
	Confidence Interval	(2-Sided) 95% 17.0 to 29.2
	Estimation Comments	[Not specified]

7. Secondary Outcome Measure:

Measure Title	Number of Subjects With Undetectable HCV RNA 12 Weeks After Last Planned Dose of Study Treatment
Measure Description	The plasma HCV RNA level was measured using Roche TaqMan HCV RNA assay. The lower limit of quantification was 25 IU/mL and the lower limit of detection was 10 IU/mL.
Time Frame	12 weeks after last planned dose of study treatment (up to Week 60)

Safety Issue?	No

Analysis Population Description

The FA set included all randomized subjects who received at least 1 dose of any study drug.

Reporting Groups

	Description
PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Placebo (PBO) matched to 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 48 weeks.
Telaprevir 8 Week, PBO 4 Week +Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 750 mg tablet thrice daily for 8 weeks, then PBO matched to Telaprevir 750 mg tablet thrice daily for 4 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 24 to 48 weeks depending on individual response to telaprevir treatment.
Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 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 24 to 48 weeks depending on individual response to telaprevir treatment.

Measured Values

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
Number of Participants Analyzed	361	364	363
Number of Subjects With Undetectable HCV RNA 12 Weeks After Last Planned Dose of Study Treatment Measure Type: Number Unit of measure: participants	161	255	275

Statistical Analysis 1 for Number of Subjects With Undetectable HCV RNA 12 Weeks After Last Planned Dose of Study Treatment

Statistical Analysis Overview	Comparison Groups	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week, Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in percentage]
	Estimated Value	25.5
	Confidence Interval	(2-Sided) 95% 18.5 to 32.4
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Number of Subjects With Undetectable HCV RNA 12 Weeks After Last Planned Dose of Study Treatment

Statistical Analysis Overview	Comparison Groups	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week, Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in percentage]
	Estimated Value	31.2
	Confidence Interval	(2-Sided) 95% 24.4 to 37.9
	Estimation Comments	[Not specified]

8. Secondary Outcome Measure:

Measure Title	Number of Subjects With Undetectable HCV RNA 24 Weeks After Last Actual Dose of Study Treatment
Measure Description	The plasma HCV RNA level was measured using Roche TaqMan HCV RNA assay. The lower limit of quantification was 25 IU/mL and the lower limit of detection was 10 IU/mL.
Time Frame	24 weeks after last actual dose of study treatment (up to Week 72)
Safety Issue?	No

Analysis Population Description

The FA set included all randomized subjects who received at least 1 dose of any study drug.

Reporting Groups

	Description
PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Placebo (PBO) matched to 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 48 weeks.
Telaprevir 8 Week, PBO 4 Week +Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 750 mg tablet thrice daily for 8 weeks, then PBO matched to Telaprevir 750 mg tablet thrice daily for 4 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 24 to 48 weeks depending on individual response to telaprevir treatment.
Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 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 24 to 48 weeks depending on individual response to telaprevir treatment.

Measured Values

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
Number of Participants Analyzed	361	364	363
Number of Subjects With Undetectable HCV RNA 24 Weeks After Last Actual Dose of Study Treatment Measure Type: Number Unit of measure: participants	158	251	274

Statistical Analysis 1 for Number of Subjects With Undetectable HCV RNA 24 Weeks After Last Actual Dose of Study Treatment

Statistical Analysis Overview	Comparison Groups	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week, Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in percentage]
	Estimated Value	25.2
	Confidence Interval	(2-Sided) 95%

		18.2 to 32.2
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Number of Subjects With Undetectable HCV RNA 24 Weeks After Last Actual Dose of Study Treatment

Statistical Analysis Overview	Comparison Groups	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week, Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in percentage]
	Estimated Value	31.7
	Confidence Interval	(2-Sided) 95% 24.9 to 38.5
	Estimation Comments	[Not specified]

9. Secondary Outcome Measure:

Measure Title	Number of Subjects With Viral Relapse Planned and Viral Relapse Actual
Measure Description	Viral relapse was defined as having detectable HCV RNA during antiviral follow-up. The plasma HCV RNA level was measured using Roche TaqMan HCV RNA assay. The lower limit of quantification was 25 IU/mL and the lower limit of detection was 10 IU/mL. For viral relapse, 2 analyses were performed: planned and actual. The planned analyses was measured from the end of treatment (EOT) visit to 24 weeks after the last planned dose of study treatment. The actual analyses was measured from the EOT visit to 24 weeks after the last actual dose of study treatment.
Time Frame	After last dose of study drug up to 24 week antiviral follow-up (up to Week 72)
Safety Issue?	No

Analysis Population Description

Analysis population included subjects who completed their assigned study drug treatment and had undetectable HCV RNA at the completion of treatment (up to Week 48).

Reporting Groups

	Description
PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Placebo (PBO) matched to 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 48 weeks.
Telaprevir 8 Week, PBO 4 Week +Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 750 mg tablet thrice daily for 8 weeks, then PBO matched to Telaprevir 750 mg tablet thrice daily for 4 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 24 to 48 weeks depending on individual response to telaprevir treatment.
Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 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 24 to 48 weeks depending on individual response to telaprevir treatment.

Measured Values

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
Number of Participants Analyzed	229	295	314
Number of Subjects With Viral Relapse Planned and Viral Relapse Actual Measure Type: Number Unit of measure: participants			
Viral Relapse Planned	64	28	27
Viral Relapse Actual	64	28	25

10. Secondary Outcome Measure:

Measure Title	Biochemical Response: Number of Subjects With Grade 3 and 4 Shifts From Baseline in Alanine Aminotransferase (ALT) and Aspartate Aminotransferase (AST) Levels
Measure Description	Criteria for grading severity (toxicity) of ALT and AST: Grade 0 (<1.25*upper limit of normal [ULN]); Grade 1 (mild=1.25 to 2.5*ULN); Grade 2 (moderate=2.6 to 5.0*ULN); Grade 3 (severe= greater than 5.0 to 20.0*ULN); Grade 4 (life-threatening= greater than 20.0*ULN). Number of subjects with Grade 3 shift (from Grade 0, Grade 1 or Grade 2 baseline) and Grade 4 shift (from Grade 0, Grade 1, Grade 2 or Grade 3 baseline) are reported. If a subject experienced more than 1 severity grade shifts during post baseline assessments, the maximum severity grade shift was considered.

Time Frame	Baseline up to Week 48
Safety Issue?	No

Analysis Population Description

The FA set included all randomized subjects who received at least 1 dose of any study drug.

Reporting Groups

	Description
PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Placebo (PBO) matched to 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 48 weeks.
Telaprevir 8 Week, PBO 4 Week +Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 750 mg tablet thrice daily for 8 weeks, then PBO matched to Telaprevir 750 mg tablet thrice daily for 4 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 24 to 48 weeks depending on individual response to telaprevir treatment.
Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 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 24 to 48 weeks depending on individual response to telaprevir treatment.

Measured Values

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
Number of Participants Analyzed	361	364	363
Biochemical Response: Number of Subjects With Grade 3 and 4 Shifts From Baseline in Alanine Aminotransferase (ALT) and Aspartate Aminotransferase (AST) Levels Measure Type: Number Unit of measure: participants			
ALT Grade 3 toxicity grade shift	12	5	6
ALT Grade 4 toxicity grade shift	0	1	0
AST Grade 3 toxicity grade shift	19	7	10
AST Grade 4 toxicity grade shift	1	0	0

11. Secondary Outcome Measure:

Measure Title	Noninvasive Markers of Fibrosis: Number of Subjects With Improvement in FibroTest Analysis
Measure Description	FibroTest analysis was a biomarker analysis test used to generate a score that was correlated with the degree of liver damage. The FibroTest score was calculated from the results of a six-parameter blood test, combining six serum markers (alpha-2-macroglobulin, haptoglobin, apolipoprotein A1, gamma-glutamyl transpeptidase, total bilirubin, and alanine transaminase). The FibroTest score (F score) may range from 0.00 (Grade F0) to 1.00 (Grade F4), where F0= no fibrosis and F4=cirrhosis. Results were presented separately for subjects who achieved SVR at 24 weeks after the last planned dose of study treatment and those who did not achieve SVR at 24 weeks after the last planned dose of study treatment. Improvement was defined as decrease of at least 1 grade relative to baseline.
Time Frame	Baseline through 24 weeks after last planned dose of study treatment (up to Week 72)
Safety Issue?	No

Analysis Population Description

The FA set included all randomized subjects who received at least 1 dose of any study drug. Here "number of participants analyzed" signifies those subjects who were evaluable for FibroTest Analysis and "n" signifies those subjects who were evaluable for FibroTest Analysis in specified category for each treatment arm, respectively.

Reporting Groups

	Description
PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Placebo (PBO) matched to 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 48 weeks.
Telaprevir 8 Week, PBO 4 Week +Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 750 mg tablet thrice daily for 8 weeks, then PBO matched to Telaprevir 750 mg tablet thrice daily for 4 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 24 to 48 weeks depending on individual response to telaprevir treatment.
Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 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 24 to 48 weeks depending on individual response to telaprevir treatment.

Measured Values

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
Number of Participants Analyzed	273	233	261

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
Noninvasive Markers of Fibrosis: Number of Subjects With Improvement in FibroTest Analysis Measure Type: Number Unit of measure: participants			
SVR achieved (136, 180, 214)	35	59	84
SVR not achieved (137, 53, 47)	31	12	12

12. Secondary Outcome Measure:

Measure Title	Fatigue Severity Scale (FSS) Total Score
Measure Description	FSS was a 9-item questionnaire where each item was scored on a scale of 1 to 7 (higher scores indicated higher influence of fatigue). FSS total score was calculated as the average of individual items on the questionnaire and FSS total score ranged from 1 to 7, where higher score indicated higher influence of fatigue.
Time Frame	Baseline, Week 4, 12, 24, 36, 48, 72
Safety Issue?	No

Analysis Population Description

The FA set included all randomized subjects who received at least 1 dose of any study drug. Here "n" signifies those participants who were evaluable for this measure at given time points for each group, respectively.

Reporting Groups

	Description
PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Placebo (PBO) matched to 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 48 weeks.
Telaprevir 8 Week, PBO 4 Week +Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 750 mg tablet thrice daily for 8 weeks, then PBO matched to Telaprevir 750 mg tablet thrice daily for 4 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 24 to 48 weeks depending on individual response to telaprevir treatment.
Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 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 24 to 48 weeks depending on individual response to telaprevir treatment.

Measured Values

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
Number of Participants Analyzed	361	364	363
Fatigue Severity Scale (FSS) Total Score Mean (Standard Deviation) Unit of measure: units on a scale			
Baseline (n=343, 351, 346)	3.0 (1.66)	3.2 (1.63)	3.0 (1.72)
Week 4 (n=334, 326, 329)	4.1 (1.74)	4.4 (1.74)	4.5 (1.75)
Week 12 (n=329, 310, 312)	4.4 (1.69)	4.4 (1.68)	4.8 (1.68)
Week 24 (n=317, 307, 304)	4.3 (1.73)	4.3 (1.71)	4.3 (1.79)
Week 36 (n=296, 282, 297)	4.1 (1.80)	3.4 (1.84)	3.3 (1.86)
Week 48 (n=286, 282, 294)	4.0 (1.82)	3.0 (1.75)	3.1 (1.85)
Week 72 (n=296, 270, 289)	2.9 (1.77)	2.6 (1.56)	2.6 (1.67)

13. Secondary 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 up to Week 48
Safety Issue?	Yes

Analysis Population Description

The FA set included all randomized subjects who received at least 1 dose of any study drug.

Reporting Groups

	Description
PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Placebo (PBO) matched to 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 48 weeks.
Telaprevir 8 Week, PBO 4 Week +Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 750 mg tablet thrice daily for 8 weeks, then PBO matched to Telaprevir 750 mg tablet thrice daily for 4 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 24 to 48 weeks depending on individual response to telaprevir treatment.
Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 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 24 to 48 weeks depending on individual response to telaprevir treatment.

Measured Values

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
Number of Participants Analyzed	361	364	363
Number of Subjects With Adverse Events (AEs) and Serious Adverse Events (SAEs) Measure Type: Number Unit of measure: participants			
AEs	354	362	361
SAEs	24	31	33

Reported Adverse Events

Time Frame	AEs and SAEs During Dosing From Baseline to 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.

	Description
PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Placebo (PBO) matched to 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 48 weeks.
Telaprevir 8 Week, PBO 4 Week +Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 750 mg tablet thrice daily for 8 weeks, then PBO matched to Telaprevir 750 mg tablet thrice daily for 4 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 24 to 48 weeks depending on individual response to telaprevir treatment.
Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 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 24 to 48 weeks depending on individual response to telaprevir treatment.

Serious Adverse Events

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	24/361 (6.65%)	31/364 (8.52%)	33/363 (9.09%)

Other Adverse Events

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

	PBO 12 Week+Peg-IFN-alfa-2a, RBV 48 Week	Telaprevir 8 Week, PBO 4 Week+Peg-IFN-alfa-2a, RBV 24/48 Week	Telaprevir 12 Week+Peg-IFN-alfa-2a, RBV 24/48 Week
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	354/361 (98.06%)	362/364 (99.45%)	361/363 (99.45%)

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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