ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: August 2, 2013

ClinicalTrials.gov ID: NCT00983853

Study Identification

Unique Protocol ID: VX08-950-110

Brief Title: Safety and Efficacy of Telaprevir in Combination With Peginterferon Alfa-2a and Ribavirin in Subjects Co-Infected With Hepatitis C Virus (HCV) and HIV

Official Title: A Phase 2a, 2-Part, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study of Telaprevir in Combination With Peginterferon Alfa-2a (Pegasys®) and Ribavirin (Copegus®) in Subjects Who Have Chronic HCV-1/HIV-1 Co-Infection and Are Treatment-Naïve for Hepatitis C

Secondary IDs:

Study Status

Record Verification: August 2013

Overall Status: Completed

Study Start: October 2009

Primary Completion: March 2012 [Actual]

Study Completion:

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: 0290 Has Expanded Access? No
Review Board:	Approval Status: Approved Approval Number: 09-195 Board Name: New England Institutional Review Board Board Affiliation: New England Institutional Review Board Phone: 781-431-7577 Email: catherine.peo@neirb.com
Data Monitoring?:	Yes
Plan to Share IPD?:	
Oversight Authorities:	United States: Food and Drug Administration Germany: Federal Institute for Drugs and Medical Devices

Study Description

Brief Summary:	The purpose of this study is to determine whether the combination of telaprevir, peginterferon alfa-2a, and ribavirin is safe and effective in treating hepatitis C virus (HCV) infection in subjects who are infected with both HCV and human immunodeficiency virus (HIV).
Detailed Description:	

Conditions

Conditions:	Hepatitis C HIV Infections
Keywords:	VX-950 INCIVEK INCIVO

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	62 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Part A The dose of ribavirin used (fixed versus weight-based) is region dependent	Drug: telaprevir or matching placebo Tablet, Oral, 750 mg, q8h, 12 weeks Biological/Vaccine: peginterferon alfa-2a Subcutaneous injection, 180 µg, once weekly, 48 weeks Drug: ribavirin (fixed dose) Tablet, Oral, 800 mg, b.i.d., 48 weeks Drug: ribavirin (weight-based dose) Tablet, Oral, 1000 mg for subjects weighing <75 kg or 1200 mg for subjects weighing ≥75 kg, b.i.d., 48 weeks
Experimental: Part B The dose of ribavirin used (fixed versus weight-based) is region dependent	Drug: telaprevir or matching placebo Tablet, Oral, 750 mg or 1125 mg, q8h, 12 weeks Biological/Vaccine: peginterferon alfa-2a Subcutaneous injection, 180 µg, once weekly, 48 weeks Drug: ribavirin (fixed dose) Tablet, Oral, 800 mg, b.i.d., 48 weeks Drug: ribavirin (weight-based dose) Tablet, Oral, 1000 mg for subjects weighing <75 kg or 1200 mg for subjects weighing ≥75 kg, b.i.d., 48 weeks

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 65 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Chronic, genotype 1, hepatitis C with detectable HCV RNA
- HIV-1 infection for >6 months
- Documentation of a liver biopsy within 1 year before the screening visit showing evidence of hepatitis (demonstrated by inflammation and/or fibrosis)

Exclusion Criteria:

- Previous treatment with any approved or investigational drug or drug regimen for the treatment of hepatitis C
- Previous treatment with interferon or ribavirin
- Evidence of hepatic decompensation in cirrhotic subjects
- Subjects who have participated in a clinical study involving administration of an investigational drug within 2 months
- Part A only: subjects who have been on a HAART regimen within 12 weeks before study start

Contacts/Locations

Study Officials: Medical Monitor
Study Director
Vertex Pharmaceuticals Incorporated

Locations: United States, Texas
Dallas, Texas, United States, 75204

United States, California
Beverly Hills, California, United States, 90211

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

United States, Florida
Orlando, Florida, United States, 32803

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

United States, California

San Francisco, California, United States, 94110

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

United States, Florida
Miami, Florida, United States, 33125

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

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

United States, California
San Diego, California, United States, 92093

Germany
Bonn-Venusberg, Germany

Hamburg, Germany

France
Paris, France

Paris, France

Spain
Madrid, Spain

Barcelona, Spain

References

Citations:

Links:

Study Data/Documents:

Participant Flow

Reporting Groups

	Description
Part A: T/PR	Drug: telaprevir tablet, oral, 750 mg, q8h, 12 weeks Biological: peginterferon alfa-2a subcutaneous injection, 180 µg, once weekly, 48 weeks Drug: ribavirin (fixed dose) tablet, oral, 800 mg, b.i.d., 48 weeks Drug: ribavirin (weight-based dose) tablet, oral, 1000 mg for subjects weighing <75 kg or 1200 mg for subjects weighing ≥75 kg, b.i.d., 48 weeks The dose of ribavirin used (fixed versus weight-based) was region dependent.
Part A: Pbo/PR	Drug: placebo tablet, oral, 750 mg, q8h, 12 weeks Biological: peginterferon alfa-2a subcutaneous injection, 180 µg, once weekly, 48 weeks Drug: ribavirin (fixed dose) tablet, oral, 800 mg, b.i.d., 48 weeks Drug: ribavirin (weight-based dose) tablet, oral, 1000 mg for subjects weighing <75 kg or 1200 mg for subjects weighing ≥75 kg, b.i.d., 48 weeks The dose of ribavirin used (fixed versus weight-based) was region dependent.
Part B: EFV-based HAART + T/PR	Drug: efavirenz, tenofovir disoproxil fumarate, and emtricitabine Drug: telaprevir tablet, oral, 750 mg, q8h, 12 weeks Biological: peginterferon alfa-2a subcutaneous injection, 180 µg, once weekly, 48 weeks Drug: ribavirin (fixed dose) tablet, oral, 800 mg, b.i.d., 48 weeks Drug: ribavirin (weight-based dose) tablet, oral, 1000 mg for subjects weighing <75 kg or 1200 mg for subjects weighing ≥75 kg, b.i.d., 48 weeks The dose of ribavirin used (fixed versus weight-based) was region dependent.

	Description
Part B: EFV-based HAART + Pbo/PR	Drug: efavirenz, tenofovir disoproxil fumarate, and emtricitabine Drug: placebo tablet, oral, 750 mg, q8h, 12 weeks Biological: peginterferon alfa-2a subcutaneous injection, 180 µg, once weekly, 48 weeks Drug: ribavirin (fixed dose) tablet, oral, 800 mg, b.i.d., 48 weeks Drug: ribavirin (weight-based dose) tablet, oral, 1000 mg for subjects weighing <75 kg or 1200 mg for subjects weighing ≥75 kg, b.i.d., 48 weeks The dose of ribavirin used (fixed versus weight-based) was region dependent.
Part B: ATV/R-based HAART + T/PR	Drug: ritonavir-boosted atazanavir, tenofovir disoproxil fumarate, and emtricitabine or lamivudine Drug: telaprevir tablet, oral, 750 mg, q8h, 12 weeks Biological: peginterferon alfa-2a subcutaneous injection, 180 µg, once weekly, 48 weeks Drug: ribavirin (fixed dose) tablet, oral, 800 mg, b.i.d., 48 weeks Drug: ribavirin (weight-based dose) tablet, oral, 1000 mg for subjects weighing <75 kg or 1200 mg for subjects weighing ≥75 kg, b.i.d., 48 weeks The dose of ribavirin used (fixed versus weight-based) was region dependent.
Part B: ATV/R-based HAART + Pbo/ PR	Drug: ritonavir-boosted atazanavir, tenofovir disoproxil fumarate, and emtricitabine or lamivudine Drug: placebo tablet, oral, 750 mg, q8h, 12 weeks Biological: peginterferon alfa-2a subcutaneous injection, 180 µg, once weekly, 48 weeks Drug: ribavirin (fixed dose) tablet, oral, 800 mg, b.i.d., 48 weeks Drug: ribavirin (weight-based dose) tablet, oral, 1000 mg for subjects weighing <75 kg or 1200 mg for subjects weighing ≥75 kg, b.i.d., 48 weeks The dose of ribavirin used (fixed versus weight-based) was region dependent.

Overall Study

	Part A: T/PR	Part A: Pbo/PR	Part B: EFV-based HAART + T/PR	Part B: EFV-based HAART + Pbo/PR	Part B: ATV/ R-based HAART + T/PR	Part B: ATV/R-based HAART + Pbo/PR
Started	7	7 [1]	17 [1]	8	15	8
Completed	6	5	14	6	12	7
Not Completed	1	2	3	2	3	1

	Part A: T/PR	Part A: Pbo/PR	Part B: EFV-based HAART + T/PR	Part B: EFV-based HAART + Pbo/PR	Part B: ATV/ R-based HAART + T/PR	Part B: ATV/R-based HAART + Pbo/PR
Lost to Follow-up	1	1	2	2	2	1
Withdrawal by Subject	0	0	1	0	1	0
Unable to come to study follow-up visits	0	1	0	0	0	0

[1] 1 subject was randomized but not dosed

Baseline Characteristics

Baseline Analysis Population Description

All randomized subjects who received at least 1 dose of study drug

Reporting Groups

	Description
Part A: T/PR	Telaprevir plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects not receiving HAART.
Part A: Pbo/PR	Placebo plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects not receiving HAART.
Part B: EFV-based HAART + T/PR	Telaprevir plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant efavirenz(EFV)-based highly active antiretroviral therapy(HAART) for the entire 48 week study.
Part B: EFV-based HAART + Pbo/PR	Placebo plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant efavirenz(EFV)-based highly active antiretroviral therapy(HAART) for the entire 48 week study.
Part B: ATV/R-based HAART + T/PR	Telaprevir plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant ritonavir-boosted atazanavir(ATV/r)-based highly active antiretroviral therapy(HAART) for the entire 48 week study.
Part B: ATV/R-based HAART + Pbo/PR	Placebo plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant ritonavir-boosted atazanavir(ATV/r)-based highly active antiretroviral therapy(HAART) for the entire 48 week study.

Baseline Measures

		Part A: T/PR	Part A: Pbo/PR	Part B: EFV-based HAART + T/PR	Part B: EFV-based HAART + Pbo/PR	Part B: ATV/ R-based HAART + T/PR	Part B: ATV/ R-based HAART + Pbo/PR	Total
Overall Number of Participants		7	6	16	8	15	8	60
Age, Continuous Median (Full Range) Unit of measure: years	Number Analyzed	7 participants	6 participants	16 participants	8 participants	15 participants	8 participants	60 participants
median (min, max)		39.4 (34 to 50)	47.5 (42 to 65)	47.5 (31 to 57)	47.0 (31 to 53)	52.0 (36 to 59)	39.0 (26 to 53)	44.5 (26 to 65)
Gender, Male/ Female Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	7 participants	6 participants	16 participants	8 participants	15 participants	8 participants	60 participants
	Female	1 14.29%	2 33.33%	0 0%	1 12.5%	2 13.33%	1 12.5%	7 11.67%
	Male	6 85.71%	4 66.67%	16 100%	7 87.5%	13 86.67%	7 87.5%	53 88.33%
Ethnicity (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	7 participants	6 participants	16 participants	8 participants	15 participants	8 participants	60 participants
	Hispanic or Latino	3 42.86%	2 33.33%	5 31.25%	1 12.5%	3 20%	3 37.5%	17 28.33%
	Not Hispanic or Latino	4 57.14%	4 66.67%	10 62.5%	7 87.5%	12 80%	5 62.5%	42 70%
	Unknown or Not Reported	0 0%	0 0%	1 6.25%	0 0%	0 0%	0 0%	1 1.67%
Race/Ethnicity, Customized Measure Type: Number Unit of measure: participants	Number Analyzed	7 participants	6 participants	16 participants	8 participants	15 participants	8 participants	60 participants
White		2	3	12	5	13	7	42
Black/African American		4	3	3	3	2	1	16

		Part A: T/PR	Part A: Pbo/PR	Part B: EFV-based HAART + T/PR	Part B: EFV-based HAART + Pbo/PR	Part B: ATV/ R-based HAART + T/PR	Part B: ATV/ R-based HAART + Pbo/PR	Total
American Indian/ Alaska Native		1	0	0	0	0	0	1
Other		0	0	1	0	0	0	1
Region of Enrollment Measure Type: Number Unit of measure: participants	Number Analyzed	7 participants	6 participants	16 participants	8 participants	15 participants	8 participants	60 participants
North America		7	5	13	8	9	4	46
United States		7	5	13	8	9	4	46
Europe		0	1	3	0	6	4	14
Germany		0	0	1	0	1	1	3
Spain		0	1	2	0	3	3	9
France		0	0	0	0	2	0	2

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Proportion of Subjects Achieving Undetectable HCV RNA at Week 12
Measure Description	
Time Frame	12 weeks after first dose of study drug
Safety Issue?	No

Analysis Population Description

Subjects who were randomized and received at least 1 dose of study drug

Reporting Groups

	Description
Part A: T/PR	Telaprevir plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects not receiving HAART.

	Description
Part A: Pbo/PR	Placebo plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects not receiving HAART.
Part B: EFV-based HAART + T/PR	Telaprevir plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant efavirenz (EFV)-based highly active antiretroviral therapy (HAART) for the entire 48 week study.
Part B: EFV-based HAART + Pbo/PR	Placebo plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant efavirenz (EFV)-based highly active antiretroviral therapy (HAART) for the entire 48 week study.
Part B: ATV/R-based HAART + T/PR	Telaprevir plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant ritonavir-boosted atazanavir (ATV/r)-based highly active antiretroviral therapy (HAART) for the entire 48 week study.
Part B: ATV/R-based HAART + Pbo/PR	Placebo plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant ritonavir-boosted atazanavir (ATV/r)-based highly active antiretroviral therapy (HAART) for the entire 48 week study.

Measured Values

	Part A: T/PR	Part A: Pbo/PR	Part B: EFV-based HAART + T/PR	Part B: EFV-based HAART + Pbo/PR	Part B: ATV/R-based HAART + T/PR	Part B: ATV/R-based HAART + Pbo/PR
Number of Participants Analyzed	7	6	16	8	15	8
Proportion of Subjects Achieving Undetectable HCV RNA at Week 12 Measure Type: Number Unit of measure: participants	6	2	14	2	10	2

2. Secondary Outcome Measure:

Measure Title	Proportion of Subjects Achieving Undetectable HCV RNA at Week 4 and Week 12
Measure Description	number of subjects with undetectable HCV RNA
Time Frame	4 and 12 weeks after the first dose of study drug
Safety Issue?	No

Analysis Population Description

Subjects who were randomized and received at least 1 dose of study drug

Reporting Groups

	Description
Part A: T/PR	Telaprevir plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects not receiving HAART.
Part A: Pbo/PR	Placebo plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects not receiving HAART.
Part B: EFV-based HAART + T/PR	Telaprevir plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant efavirenz (EFV)-based highly active antiretroviral therapy (HAART) for the entire 48 week study.
Part B: EFV-based HAART + Pbo/PR	Placebo plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant efavirenz (EFV)-based highly active antiretroviral therapy (HAART) for the entire 48 week study.
Part B: ATV/R-based HAART + T/PR	Telaprevir plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant ritonavir-boosted atazanavir (ATV/r)-based highly active antiretroviral therapy (HAART) for the entire 48 week study.
Part B: ATV/R-based HAART + Pbo/PR	Placebo plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant ritonavir-boosted atazanavir (ATV/r)-based highly active antiretroviral therapy (HAART) for the entire 48 week study.

Measured Values

	Part A: T/PR	Part A: Pbo/PR	Part B: EFV-based HAART + T/PR	Part B: EFV-based HAART + Pbo/PR	Part B: ATV/R-based HAART + T/PR	Part B: ATV/R-based HAART + Pbo/PR
Number of Participants Analyzed	7	6	16	8	15	8
Proportion of Subjects Achieving Undetectable HCV RNA at Week 4 and Week 12 Measure Type: Number Unit of measure: participants						
Week 4 (RVR)	5	0	12	0	9	0
Weeks 4 and 12 (eRVR)	4	0	12	0	7	0

3. Secondary Outcome Measure:

Measure Title	Proportion of Subjects Who Have Undetectable HCV RNA 12 Weeks (SVR12) and 24 Weeks (SVR24) After Last Planned Dose of Study Treatment
Measure Description	
Time Frame	12 weeks after last dose of study drug
Safety Issue?	No

Analysis Population Description

subjects who received at least 1 dose of study drug.

Reporting Groups

	Description
Part A: T/PR	Telaprevir plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects not receiving HAART.
Part A: Pbo/PR	Placebo plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects not receiving HAART.
Part B: EFV-based HAART + T/PR	Telaprevir plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant efavirenz (EFV)-based highly active antiretroviral therapy (HAART) for the entire 48 week study.
Part B: EFV-based HAART + Pbo/PR	Placebo plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant efavirenz (EFV)-based highly active antiretroviral therapy (HAART) for the entire 48 week study.
Part B: ATV/R-based HAART + T/PR	Telaprevir plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant ritonavir-boosted atazanavir (ATV/r)-based highly active antiretroviral therapy (HAART) for the entire 48 week study.
Part B: ATV/R-based HAART + Pbo/PR	Placebo plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant ritonavir-boosted atazanavir (ATV/r)-based highly active antiretroviral therapy (HAART) for the entire 48 week study.

Measured Values

	Part A: T/PR	Part A: Pbo/PR	Part B: EFV-based HAART + T/PR	Part B: EFV-based HAART + Pbo/PR	Part B: ATV/R-based HAART + T/PR	Part B: ATV/R-based HAART + Pbo/PR
Number of Participants Analyzed	7	6	16	8	15	8

	Part A: T/PR	Part A: Pbo/PR	Part B: EFV-based HAART + T/PR	Part B: EFV-based HAART + Pbo/PR	Part B: ATV/R-based HAART + T/PR	Part B: ATV/R-based HAART + Pbo/PR
Proportion of Subjects Who Have Undetectable HCV RNA 12 Weeks (SVR12) and 24 Weeks (SVR24) After Last Planned Dose of Study Treatment Measure Type: Number Unit of measure: participants						
SVR12	5	2	11	4	12	4
SVR24	5	2	11	4	12	4

4. Secondary Outcome Measure:

Measure Title	Effect of Efavirenz-based (EFV) and Atazanavir-based (ATV/r) Highly Active Antiretroviral Therapy(HAART) on Telaprevir Exposure
Measure Description	
Time Frame	through 12 weeks after first dose of study drug
Safety Issue?	No

Analysis Population Description

subjects with available plasma concentration data

Reporting Groups

	Description
EFV-based (Test, N=15) vs No HAART (Reference, N=7)	
ATV/R-based (Test, N=13) vs No HAART (Reference, N=7)	

Measured Values

	EFV-based (Test, N=15) vs No HAART (Reference, N=7)	ATV/R-based (Test, N=13) vs No HAART (Reference, N=7)
Number of Participants Analyzed	15	13

	EFV-based (Test, N=15) vs No HAART (Reference, N=7)	ATV/R-based (Test, N=13) vs No HAART (Reference, N=7)
Effect of Efavirenz-based (EFV) and Atazanavir-based (ATV/r) Highly Active Antiretroviral Therapy(HAART) on Telaprevir Exposure Least Squares Mean (90% Confidence Interval) Unit of measure: ratio (test/reference)		
Cmin	0.8842 (0.5467 to 1.4300)	1.3059 (0.7981 to 2.1367)
Cavg	0.9610 (0.6615 to 1.3961)	1.0930 (0.7456 to 1.6023)
Cmax	1.0061 (0.7306 to 1.3855)	1.0075 (0.7260 to 1.3982)

5. Secondary Outcome Measure:

Measure Title	Median Trough Plasma Concentration (Ctrough) Ratios of Efavirenz and Tenofovir (Part B Only, Subjects on EFV-based HAART)
Measure Description	Ctrough ratio of HAART medication with telaprevir (test) and without telaprevir (reference)
Time Frame	through 12 weeks after first dose of study drug
Safety Issue?	No

Analysis Population Description
subjects with available concentration data

Reporting Groups

	Description
T/PR	Telaprevir plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant efavirenz(EFV)-based highly active antiretroviral therapy(HAART) for the entire 48 week study.
Pbo/PR	Placebo plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant efavirenz(EFV)-based highly active antiretroviral therapy(HAART) for the entire 48 week study.

Measured Values

	T/PR	Pbo/PR
Number of Participants Analyzed	14	8

	T/PR	Pbo/PR
Median Trough Plasma Concentration (Ctrough) Ratios of Efavirenz and Tenofovir (Part B Only, Subjects on EFV-based HAART) Median (Full Range) Unit of measure: ratio (test/reference)		
Efavirenz	0.94 (0.42 to 2.84)	0.79 (0.48 to 1.48)
Tenofovir	1.06 (0.46 to 17.4)	0.64 (0.30 to 2.01)

6. Secondary Outcome Measure:

Measure Title	Median Trough Plasma Concentration (Ctrough) Ratios of Atazanavir (ATZ), Ritonavir, and Tenofovir (Part B Only, Subjects on ATV-based HAART)
Measure Description	Ctrough of HAART medication with telaprevir (test) and without telaprevir (reference)
Time Frame	through 12 weeks after first dose of study drug
Safety Issue?	No

Analysis Population Description
subjects with available concentration data

Reporting Groups

	Description
T/PR	Telaprevir plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant ritonavir-boosted atazanavir(ATV/r)-based highly active antiretroviral therapy(HAART) for the entire 48 week study.
Pbo/PR	Placebo plus peginterferon alfa-2a and ribavirin for 12 weeks, followed by 36 weeks of peginterferon alfa-2a and ribavirin. Subjects receiving concomitant ritonavir-boosted atazanavir(ATV/r)-based highly active antiretroviral therapy(HAART) for the entire 48 week study.

Measured Values

	T/PR	Pbo/PR
Number of Participants Analyzed	13	7

	T/PR	Pbo/PR
Median Trough Plasma Concentration (Ctrough) Ratios of Atazanavir (ATZ), Ritonavir, and Tenofovir (Part B Only, Subjects on ATV-based HAART) Median (Full Range) Unit of measure: ratio (test/reference)		
Atazanavir (N=12 T/PR, N=6 Pbo/PR)	1.16 (0.39 to 45.0)	1.03 (0.49 to 2.05)
Tenofovir (N=13 T/PR, N=7 Pbo/PR)	0.75 (0.28 to 40.7)	0.93 (0.55 to 1.68)
Ritonavir (N=9 T/PR, N=7 Pbo/PR)	0.72 (0.08 to 4.40)	0.74 (0.21 to 4.20)

Reported Adverse Events

Time Frame	first dose of study drug until 4 weeks after the last dose of study drug
Additional Description	[Not specified]

Reporting Groups

	Description
T/PR	Pooled T/PR from Part A and Part B
Total PR	Pooled PR from Part A and Part B

Serious Adverse Events

	T/PR	Total PR
	Affected/At Risk (%)	Affected/At Risk (%)
Total	7/38 (18.42%)	2/22 (9.09%)

Other Adverse Events

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

	T/PR	Total PR
	Affected/At Risk (%)	Affected/At Risk (%)
Total	38/38 (100%)	22/22 (100%)

More Information

Certain Agreements:

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

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

Results Point of Contact:

Name/Official Title: Medical Monitor
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