ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 10/10/2013

ClinicalTrials.gov ID: NCT00529568

Study Identification

Unique Protocol ID:	TPL108390
Brief Title:	Eltrombopag To Initiate And Maintain Interferon Antiviral Treatment To Benefit Subjects With Hepatitis C Liver Disease
Official Title:	Randomised, Placebo-controlled, Multi-centre Study to Assess the Efficacy and Safety of Eltrombopag in Thrombocytopenic Subjects With Hepatitis C Virus (HCV) Infection Who Are Otherwise Eligible to Initiate Antiviral Therapy (Peginterferon Alfa-2b Plus Ribavirin)
Secondary IDs:	

Study Status

Record Verification:	March 2013
Overall Status:	Completed
Study Start:	October 2007
Primary Completion:	August 2011 [Actual]
Study Completion:	August 2011 [Actual]

Sponsor/Collaborators

Sponsor:	GlaxoSmithKline
Responsible Party:	Sponsor
Collaborators:	

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: 75,863 Serial Number: tbd Has Expanded Access? No
Review Board:	Approval Status: Approved Approval Number: 20071047 Board Name: Western Institutional Review Board Board Affiliation: Phone: 001 800 562 4789 Email:
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	United Kingdom: Medicines and Healthcare Products Regulatory Agency United States: Food and Drug Administration

Study Description

Brief Summary:	The purpose of this study is to assess the ability of eltrombopag to maintain a platelet count sufficient to facilitate initiation of antiviral therapy, to minimise antiviral therapy dose reductions and to avoid permanent discontinuation of antiviral therapy. The clinical benefit of eltrombopag will be measured by the proportion of subjects who are able to achieve a Sustained Virological Response (SVR).
Detailed Description:	

Conditions

Conditions:	Hepatitis C, Chronic
Keywords:	hepatitis C ribavirin Hepatitis C-related thrombocytopenia thrombopoietin peginterferon alfa-2b platelets

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Investigator)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	759 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: eltrombopag active treatment arm	Drug: eltrombopag double-blind active treatment daily oral administation at dose of 25, 50, 75, or 100 mg Other Names: • eltrombopag
Placebo Comparator: placebo placebo control arm	Drug: placebo double-blind matched placebo control daily oral administration

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:

Male and female subjects, >18 years Evidence of chronic hepatitis C virus (HCV) infection Subjects who are appropriate candidates for peginterferon (pegIFN) and ribavirin antiviral therapy A platelet count of <75,000/mcL Haemoglobin >11.0g/dL for men or >10.0g/dL for women Absolute neutrophil count (ANC) >750/mm3 and no history of infections associated with neutropenia Creatinine clearance >50mL/minute All fertile males and females must use two forms of effective contraception between them during treatment and during the 24 weeks after treatment end Subject is able to understand, consent and comply with protocol requirements and instructions and is likely to complete the study as planned

Exclusion criteria:

Non-responders to previous treatment with pegIFN and ribavirin who failed to achieve a sustained virologic response (SVR) for reasons other than thrombocytopenia, despite an optimal course (dose and duration) of combination therapy with pegIFN and ribavirin Decompensated liver disease, e.g. Child-Pugh score >6 or history of ascites or hepatic encephalopathy or current evidence of ascites Known hypersensitivity, intolerance or allergy to interferon (IFN), ribavirin, eltrombopag or any of their ingredients Serious cardiac, cerebrovascular, or pulmonary disease that would preclude treatment with pegIFN and ribavirin

Subjects with a history of any one of the following:

Suicide attempt or hospitalisation for depression in the past 5 years Any current severe or poorly controlled psychiatric disorder

The following subjects are eligible for study participation, but must be assessed and followed (if recommended) by a mental health professional:

- Subjects who have had a severe or poorly controlled psychiatric disorder more than 6 months ago but less than 5 years ago
- Seizure disorder that has not been well controlled History of clinically significant bleeding from oesophageal or gastric varices Subjects with haemoglobinopathies, e.g. sickle cell anaemia, thalassemia major Any prior history of arterial or venous thrombosis AND two or more of the following risk factors: hereditary thrombophilic disorders (e.g. Factor V Leiden, ATIII deficiency, etc), hormone replacement therapy, systemic contraception (containing estrogen), smoking, diabetes, hypercholesterolemia, medication for hypertension or cancer Pre-existing cardiac disease (New York Heart Association (NYHA) Grade III/IV), or arrhythmias known to involve the risk of thromboembolic events, or corrected QT interval (QTc) >450 msec Evidence of hepatocellular carcinoma Laboratory evidence of infection with human immunodeficiency virus (HIV) or active Hepatitis B Virus (HBV) infection Any disease condition associated with active bleeding or requiring anticoagulation with heparin or warfarin Therapy with any anti-neoplastic or immuno-modulatory treatment <6 months prior to the first dose of eltrombopag.

Subjects who have had a malignancy diagnosed and/or treated within the past 5 years, except for subjects with localised basal or squamous cell carcinoma treated by local excision or subjects with malignancies who have been adequately treated and, in the opinion of the oncologist, have an excellent chance of cancer-free survival Pregnant or nursing women Males with a female partner who is pregnant History of alcohol/drug abuse or dependence within 6 months of the study start (unless participating in a controlled rehabilitation programme) Treatment with an investigational drug or IFN within 30 days or 5 half-lives (whichever is longer) of the screening visit History of platelet clumping that prevents reliable measurement of platelet counts History of major organ transplantation with an existing functional graft Thyroid dysfunction not adequately controlled Subjects planning to have cataract surgery Evidence of portal vein thrombosis on abdominal imaging within 3 months of the baseline visit

Contacts/Locations

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References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Pre-Assignment Details	The number of enrolled participants in the protocol record (n=759) reflects the number of participants randomized to double-blind treatment after completing the Open-label Phase.

Reporting Groups

	Description
Eltrombopag: Open-label Phase	Participants with a platelet count of <75 giga (10^9) cells per liter (Gi/L) initially received eltrombopag 25 milligrams (mg) once daily (QD) for 2 weeks. After 2 weeks, if the platelet count was <100 Gi/L, participants underwent dose escalation to 50 mg QD for 2 weeks. If platelet counts still remained <100 Gi/L, further dose escalations to 75 mg QD (up to 2 weeks) and 100 mg QD (up to a maximum of 3 weeks) were allowed. Participants who achieved platelet counts >=100 Gi/L during the Open-label Phase (maximum of up to 9 weeks) were eligible to enter the Double-blind (DB) Antiviral Treatment Phase, whereas those who failed to reach platelet counts >=100 Gi/L were discontinued from eltrombopag and had to attend the post-treatment follow-up visits.
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Open-label Pre-Antiviral Treatment Phase

	Eltrombopag: Open-label Phase	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Started	805	0	0

	Eltrombopag: Open-label Phase	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Completed	759	0	0
Not Completed	46	0	0
Adverse Event	5	0	0
Lost to Follow-up	12	0	0
Protocol Violation	5	0	0
Physician Decision	8	0	0
Insufficient Platelet Response	13	0	0
Withdrawal by Subject	3	0	0

Double-bilnd Antiviral Treatment Phase

	Eltrombopag: Open-label Phase	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Started	0	253	506
Completed	0	205	404
Not Completed	0	48	102
Adverse Event	0	10	27
Protocol Violation	0	1	0
Lost to Follow-up	0	15	48
Physician Decision	0	5	8
Withdrawal by Subject	0	17	19

Baseline Characteristics

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

	Description
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Baseline Measures

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase	Total
Number of Participants	253	506	759
Age, Continuous [1] [units: Years] Mean (Standard Deviation)	52.0 (9.15)	52.4 (8.61)	52.3 (8.79)
Gender, Male/Female [1] [units: Participants]			
Female	93	185	278
Male	160	321	481
Race/Ethnicity, Customized [2] [units: participants]			
African American (A)/African	4	8	12
American Indian or Alaska Native	0	1	1
White (W)	188	388	576
Central/South Asian	16	43	59
Japanese/East Asian /South East Asian	45	64	109
American Indian or Alaska Native and White	0	1	1
African A/African and A Indian/Alaska Native and W	0	1	1

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase	Total
Number of participants categorized into the indicated genotype for Hepatitic C Virus (HCV) [3] [units: participants]			
Genotype 1	160	320	480
Genotype 2	28	40	68
Genotype 3	47	113	160
Genotype 4	17	30	47
Genotype 5	0	0	0
Genotype 6	0	1	1
Genotype 7	0	0	0
Missing	1	2	3
Number of participants categorized into the indicated Child-Pugh (CP) Class [4] [units: participants]			
Class A	242	487	729
Class B	11	17	28
Class C	0	0	0
Missing	0	2	2
Number of participants with or without previous interferon (IFN) use [5] [units: participants]			
Naïve	182	347	529
Experienced	71	159	230
Number of participants with the indicated FibroTest/Acti Test (FibroSURE) score [6] [units: participants]			
Score: F0/F1/F2	19	46	65

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase	Total
Score: F3/F4	199	405	604
Missing	35	55	90
Number of participants with normal or elevated Baseline values for Alanine Aminotransferase (ALT) [7] [units: participants]			
Normal	49	113	162
Elevated	204	393	597
Baseline HCV Ribonucleic Acid (RNA) [8] [units: International Units per milliliter] Mean (Standard Deviation)	1656788.0 (2564763.45)	1702729.6 (3066411.11)	1687415.8 (2907191.97)
Baseline Platelet Count [9] [units: Giga (10^9) cells per liter (Gi/L)] Mean (Standard Deviation)	56.56 (13.571)	56.85 (13.311)	56.75 (13.390)

[1] Baseline characteristics were collected for the Intent-to-Treat (ITT) Population, which included all randomized participants in the Double-blind (DB) Phase of the study.

[2] Baseline characteristics were collected for the ITT Population, which included all randomized participants in the DB Phase of the study.

[3] Baseline characteristics were collected for the ITT Population, which included all randomized participants in the DB Phase of the study. The HCV is a small, enveloped, single-stranded, positive-sense ribonucleic acid (RNA) virus. There are seven major genotypes of HCV, which are indicated numerically from Genotype 1 to 7.

[4] The CP score (ranging from 5 to 15, with 5 being mild and 15 being severe), calculated based on total bilirubin, serum albumin, international normalized ratio, ascites, and hepatic encephalopathy, is used to assess the severity of liver disease. A CP score of 5-6 = Class A (mild), 7-9 = Class B (moderate), and >=10 = Class C (severe).

[5] Baseline characteristics were collected for the ITT Population, which included all randomized participants in the DB Phase of the study. Participants at Baseline were classified as not having used IFN previously (Naïve) or having used IFN previously (Experienced).

[6] FibroSURE is a noninvasive blood test that combines the quantitative results of 6 serum biochemical markers (α2-macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, γ-glutamyl transpeptidase [GGT], and ALT) with a participant's age and gender to generate a measure of liver fibrosis/cirrhosis and necroinflammatory activity. It provides a numerical quantitative estimate of liver fibrosis ranging from 0.00 to 1.00, corresponding to the Metavir scoring system of stages F0 to F4 (F0, no fibrosis [F]; F1, portal F; F2, bridging F with few septa; F3, bridging F with many septa; F4=cirrhosis).

[7] Baseline characteristics were collected for the ITT Population, which included all randomized participants in the DB Phase of the study. The normal range of ALT is 0 to 48 International Units per Liter (IU/L).

[8] Baseline characteristics were collected for the ITT Population, which included all randomized participants in the DB Phase of the study. HCV RNA was assessed at baseline of the DB Phase. Data are missing for three participants in the Eltrombopag+Antiviral Therapy treatment group.

[9] Baseline characteristics were collected for the ITT Population, which included all randomized participants in the DB Phase of the study. Platelet count eligibility was confirmed at the Baseline visit, prior to administration of eltrombopag, and was defined as the average of the screening and baseline counts, which must be <75 Gi/L.

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Participants With Sustained Virologic Response (SVR) in the Double-blind (DB) Antiviral Treatment Phase
Measure Description	Participants with SVR are defined as those with non-detectable Hepatitis C Virus (HCV) ribonucleic acid (RNA) at the end of treatment and all subsequent planned visits up to 24 weeks post-completion of the treatment period of the DB Phase.
Time Frame	From Baseline up to Week 48 or Week 72 (for participants with Genotype 2/3) or up to Week 72 (for participants with Non-Genotype 2/3)
Safety Issue?	No

Analysis Population Description

Intent-to-Treat (ITT) Population: all participants randomized in the DB Phase

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	253	506
Number of Participants With Sustained Virologic Response (SVR) in the Double-blind (DB) Antiviral Treatment Phase [units: participants]	32	97

Statistical Analysis 1 for Number of Participants With Sustained Virologic Response (SVR) in the Double-blind (DB) Antiviral Treatment Phase

Statistical Analysis Overview	Comparison Groups	Placebo+Antiviral Therapy: DB Phase, Eltrombopag+Antiviral Therapy: DB Phase
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0202
	Comments	Stratified Cochran-Mantel-Haenszel (CMH) chi-square test adjusted for the randomization strata
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Percentage difference in SVR]
	Estimated Value	6.0
	Confidence Interval	(2-Sided) 95% 1.2 to 10.9
	Estimation Comments	The estimated value reflects the percentage of participants with SVR in the eltrombopag group minus the percentage of participants with SVR in the placebo group. Adjusted for the actual strata: HCV genotype, baseline platelet count, and HCV RNA.

2. Secondary Outcome Measure:

Measure Title	Number of Participants Whose Platelet Count Increased From a Baseline Count of <75 Gi/L to a Count Greater Than or Equal to (>=) 100 Giga (10^9) Cells Per Liter (Gi/L) During the Open-label (OL) Pre-Antiviral Treatment Phase
Measure Description	Participants were assessed for a shift from a baseline platelet count of <75 Gi/L to a count >=100 Gi/L during the OL Phase (up to 9 weeks). Local laboratories were used for platelet function tests. Platelet counts were measured by blood draw.
Time Frame	From Baseline up to Week 9 in the OL Phase
Safety Issue?	No

Analysis Population Description

Safety Population: all participants who had received study drug in the OL Phase

Reporting Groups

	Description
Eltrombopag: OL Phase	Participants with a platelet count of <75 giga (10^9) cells per liter (Gi/L) initially received eltrombopag 25 milligrams (mg) once daily (QD) for 2 weeks. After 2 weeks, if the platelet count was <100 Gi/L, participants underwent dose escalation to 50 mg QD for 2 weeks. If platelet counts still remained <100 Gi/L, further dose escalations to 75 mg QD (up to 2 weeks) and 100 mg QD (up to a maximum of 3 weeks) were allowed. Participants who achieved platelet counts >=100 Gi/L during the OL Phase (maximum of up to 9 weeks) were eligible to enter the Double-blind (DB) Antiviral Treatment Phase, whereas those who failed to reach platelet counts >=100 Gi/L were discontinued from eltrombopag and had to attend the post-treatment follow-up visits.

Measured Values

	Eltrombopag: OL Phase
Number of Participants Analyzed	805
Number of Participants Whose Platelet Count Increased From a Baseline Count of <75 Gi/L to a Count Greater Than or Equal to (>=) 100 Giga (10^9) Cells Per Liter (Gi/L) During the Open-label (OL) Pre-Antiviral Treatment Phase [units: participants]	773

3. Secondary Outcome Measure:

Measure Title	Number of Participants Receiving the Indicated Doses of Eltrombopag in the OL Phase Who Initiated Antiviral Therapy (Peginterferon Alfa-2a and Ribavirin) in the DB Phase
Measure Description	In the OL Phase, participants initially received the lowest dose of eltrombopag (25 mg QD) for 2 weeks. If after this time the platelet count was <100 Gi/L, participants underwent sequential dose escalation to the next highest dose (50 mg QD for up to 2 weeks), with further dose escalations to 75 mg QD (up to 2 weeks) and 100 mg QD (up to a maximum of 3 weeks) if platelet counts remained <100 Gi/L. Participants who achieved platelet counts >=100 Gi/L when receiving any of the eltrombopag doses in the OL Phase initiated antiviral therapy in the DB Phase.
Time Frame	From Baseline up to Week 9 in the OL Phase
Safety Issue?	No

Analysis Population Description

Safety Population. Participants with a platelet count >=100 Gi/L and who initiated antiviral therapy during the DB Phase were analyzed.

Reporting Groups

	Description
Eltrombopag: OL Phase	Participants with a platelet count of <75 giga (10^9) cells per liter (Gi/L) initially received eltrombopag 25 milligrams (mg) once daily (QD) for 2 weeks. After 2 weeks, if the platelet count was <100 Gi/L, participants underwent dose escalation to 50 mg QD for 2 weeks. If platelet counts still remained <100 Gi/L, further dose escalations to 75 mg QD (up to 2 weeks) and 100 mg QD (up to a maximum of 3 weeks) were allowed. Participants who achieved platelet counts >=100 Gi/L during the OL Phase (maximum of up to 9 weeks) were eligible to enter the Double-blind (DB) Antiviral Treatment Phase, whereas those who failed to reach platelet counts >=100 Gi/L were discontinued from eltrombopag and had to attend the post-treatment follow-up visits.

Measured Values

	Eltrombopag: OL Phase
Number of Participants Analyzed	759
Number of Participants Receiving the Indicated Doses of Eltrombopag in the OL Phase Who Initiated Antiviral Therapy (Peginterferon Alfa-2a and Ribavirin) in the DB Phase [units: participants]	
25 mg	443
50 mg	208
75 mg	77
100 mg	31

4. Secondary Outcome Measure:

Measure Title	Median Platelet Count at the Indicated Time Points During the OL Phase
Measure Description	Blood taken from peripheral blood vessels was used for the measurement of platelet counts. The Last On Treatment assessment refers to the actual last treatment assessment, not necessarily to the End of Treatment assessment entered by the Investigator.
Time Frame	OL Phase: Baseline; Day 1; Weeks 1, 2, 3, 4, 5, 6, 7, 8, and 9; Antiviral Baseline (up to Week 10); End of Treatment (up to Week 48); 4-week Follow-up (FU) (up to Week 62); 12-week FU (up to Week 70); and 24-week FU (up to Week 82)
Safety Issue?	No

Analysis Population Description

Safety Population. Only those participants contributing data at the indicated time points were analyzed.

Reporting Groups

	Description
Eltrombopag: OL Phase	Participants with a platelet count of <75 giga (10^9) cells per liter (Gi/L) initially received eltrombopag 25 milligrams (mg) once daily (QD) for 2 weeks. After 2 weeks, if the platelet count was <100 Gi/L, participants underwent dose escalation to 50 mg QD for 2 weeks. If platelet counts still remained <100 Gi/L, further dose escalations to 75 mg QD (up to 2 weeks) and 100 mg QD (up to a maximum of 3 weeks) were allowed. Participants who achieved platelet counts >=100 Gi/L during the OL Phase (maximum of up to 9 weeks) were eligible to enter the Double-blind (DB) Antiviral Treatment Phase, whereas those who failed to reach platelet counts >=100 Gi/L were discontinued from eltrombopag and had to attend the post-treatment follow-up visits.

Measured Values

	Eltrombopag: OL Phase
Number of Participants Analyzed	797
Median Platelet Count at the Indicated Time Points During the OL Phase [units: Gi/L] Median (Full Range)	
Baseline, n=797	59.0 (12 to 95)
Day 1, n=714	58.0 (5 to 117)
Week 1, n=791	77.0 (5 to 223)
Week 2, n=530	93.0 (9 to 489)
Week 3, n=288	89.0 (10 to 504)
Week 4, n=161	90.0 (10 to 280)
Week 5, n=98	92.0 (9 to 252)
Week 6, n=55	86.0 (14 to 138)
Week 7, n=35	78.0 (11 to 136)
Week 8, n=24	87.5 (15 to 146)
Week 9, n=4	85.5 (66 to 107)
Antiviral Baseline, n=48	131.5 (76 to 274)
End of Treatment/Withdrawal, n=22	76.5 (13 to 257)
Last on Treatment, n=39	87.0 (13 to 267)
Week 4 Follow-Up, n=20	42.0 (11 to 156)
Week 12 Follow-Up, n=15	43.0 (8 to 91)

	Eltrombopag: OL Phase
Week 24 Follow-Up, n=14	41.0 (13 to 87)

5. Secondary Outcome Measure:

Measure Title	Median Platelet Count at the Indicated Time Points During the DB Phase
Measure Description	Blood taken from peripheral blood vessels was used for the measurement of platelet counts. The Last On Treatment assessment refers to the actual last treatment assessment, not necessarily to the End of Treatment assessment entered by the Investigator.
Time Frame	DB Phase: Baseline; Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24, 28, 32, 36, 40, and 44; End of Treatment (up to Week 48); 4-week Follow-up (FU) (up to Week 52); 12-week FU (up to Week 60); and 24-week FU (up to Week 72)
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants contributing data at the indicated time points were analyzed.

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	252	505
Median Platelet Count at the Indicated Time Points During the DB Phase [units: Gi/L] Median (Full Range)		
Baseline, n=238, 460	140.0 (63 to 365)	136.0 (43 to 400)
Week 1, n=247, 494	120.0 (42 to 366)	116.0 (46 to 466)

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Week 2, n=244, 492	89.5 (27 to 318)	124.0 (38 to 553)
Week 4, n=228, 487	51.0 (20 to 180)	105 (19 to 389)
Week 6, n=206, 473	49.5 (20 to 200)	100.0 (22 to 417)
Week 8, n=192, 473	50.0 (10 to 191)	100.0 (19 to 486)
Week 12, n=176, 451	49.7 (21 to 264)	104.0 (10 to 444)
Week 16, n=145, 405	48.0 (20 to 262)	102.0 (13 to 365)
Week 20, n=134, 378	50.0 (23 to 257)	103.0 (21 to 373)
Week 24, n=99, 263	49.0 (19 to 200)	102.0 (18 to 448)
Week 28, n=74, 212	52.5 (22 to 193)	102.0 (20 to 355)
Week 32, n=67, 199	49.0 (22 to 195)	107.0 (14 to 295)
Week 36, n=63, 185	50.0 (16 to 198)	106.0 (29 to 268)
Week 40, n=58, 174	53.7 (19 to 195)	106.5 (10 to 351)
Week 44, n=59, 168	53.0 (26 to 197)	108.7 (26 to 330)
End of Treatment/Withdrawal, n=240, 468	51.0 (10 to 275)	106.5 (10 to 445)
Last on Treatment, n=253, 505	50.0 (17 to 300)	105.0 (10 to 330)
4 week follow up, n=221, 424	63.0 (4 to 225)	89.0 (12 to 333)
12 week follow up, n=209, 430	57.0 (15 to 285)	62.0 (8 to 280)
24 week follow up, n=201, 395	57.0 (8 to 231)	59.0 (4 to 297)

6. Secondary Outcome Measure:

Measure Title	Number of Participants in the Indicated Categories for Minimum Platelet Count With Antiviral Therapy
Measure Description	The minimum platelet count with antiviral therapy was categorized as follows: <25 Gi/L; >=25 to <50 Gi/L; >=50 to <90 Gi/L; >=90 to <150 Gi/L; >=150 Gi/L to <200 Gi/L; >=200 Gi/L to <400 Gi/L; and >=400 Gi/L.
Time Frame	From Baseline up to Week 48 or Week 72 (for participants with Genotype 2/3) or up to Week 72 (for participants with Non-Genotype 2/3)
Safety Issue?	No

Analysis Population Description
ITT Population

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	253	506
Number of Participants in the Indicated Categories for Minimum Platelet Count With Antiviral Therapy [units: participants]		
<25 Gi/L	34	20
>=25 to <50 Gi/L	159	76
>=50 to <90 Gi/L	49	263
>=90 to <150 Gi/L	10	135
>=150 to <200 Gi/L	0	8
>=200 to <400 Gi/L	0	4
>=400 Gi/L	0	0
Missing	1	0

7. Secondary Outcome Measure:

Measure Title	Number of Participants With Rapid Virological Response (RVR) and Extended RVR (eRVR) During the DB Phase
Measure Description	RVR is defined as the absence of detectable HCV RNA after 4 weeks of antiviral treatment. eRVR is defined as the absence of detectable HCV RNA after 4 weeks of antiviral treatment that persisted through Week 12.

Time Frame	From Baseline up to Week 48 or Week 72 (for participants with Genotype 2/3) or up to Week 72 (for participants with Non-Genotype 2/3)
Safety Issue?	No

Analysis Population Description
ITT Population

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	253	506
Number of Participants With Rapid Virological Response (RVR) and Extended RVR (eRVR) During the DB Phase [units: participants]		
RVR	34	78
eRVR	27	69

8. Secondary Outcome Measure:

Measure Title	Number of Participants With Early Virological Response (EVR) and Complete EVR (cEVR) During the DB Phase
Measure Description	EVR is defined as a clinically significant reduction from Baseline in HCV RNA (>=2 log10 drop or undetectable) after 12 weeks of antiviral treatment. cEVR is defined as undetectable HCV RNA after 12 weeks of antiviral treatment.
Time Frame	From Baseline up to Week 48 or Week 72 (for participants with Genotype 2/3) or up to Week 72 (for participants with Non-Genotype 2/3)
Safety Issue?	No

Analysis Population Description
ITT Population

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	253	506
Number of Participants With Early Virological Response (EVR) and Complete EVR (cEVR) During the DB Phase [units: participants]		
EVR	103	313
cEVR	57	174

9. Secondary Outcome Measure:

Measure Title	Number of Participants With End of Treatment Response (ETR) and Sustained Virological Response at Week 12 of Follow-up (SVR12) During the DB Phase
Measure Description	ETR is defined as the absence of detectable HCV RNA at the end of antiviral treatment. SVR12 is defined as the absence of detectable HCV RNA at the end of antiviral treatment and the 12-week follow-up assessment.
Time Frame	From Baseline up to Week 48 or Week 72 (for participants with Genotype 2/3) or up to Week 72 (for participants with Non-Genotype 2/3)
Safety Issue?	No

Analysis Population Description
ITT Population

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	253	506
Number of Participants With End of Treatment Response (ETR) and Sustained Virological Response at Week 12 of Follow-up (SVR12) During the DB Phase [units: participants]		
ETR	59	190
SVR12	29	106

10. Secondary Outcome Measure:

Measure Title	Number of Participants in the Indicated Categories for Antiviral Therapy Dose Reductions in the DB Phase
Measure Description	Participants were assigned a score equal to the number of times their dose of antiviral therapy (peginterferon or ribavirin) was reduced (0=no dose reductions [DRs]; 1=one DR; 2=two DRs; 3=three DRs; >3=more than three DRs). When possible, every effort was made to maintain the recommended dose of antiviral therapy for the treatment duration in the DB Phase. However, when dose modification of antiviral therapy was required due to safety concerns, it was performed by the Investigator as per the region-specific product labels of peginterferon and ribavirin.
Time Frame	From Baseline up to Week 48 or Week 72 (for participants with Genotype 2/3) or up to Week 72 (for participants with Non-Genotype 2/3)
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	253	506
Number of Participants in the Indicated Categories for Antiviral Therapy Dose Reductions in the DB Phase [units: participants]		
0	68	231
1	76	101
2	40	75
3	34	47
>3	35	52

11. Secondary Outcome Measure:

Measure Title	Time to First Dose Reduction of Peginterferon Alfa-2a and Ribavirin Therapy in the DB Phase
Measure Description	Time to first dose reduction was calculated as the time period from the first dose to the first dose reduction.
Time Frame	From Baseline up to Week 48 or Week 72 (for participants with Genotype 2/3) or up to Week 72 (for participants with Non-Genotype 2/3)
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants with dose reductions were analyzed.

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	171	208
Time to First Dose Reduction of Peginterferon Alfa-2a and Ribavirin Therapy in the DB Phase [units: weeks] Mean (Standard Deviation)		
Peginterferon alfa-2a dose reduction, n=171, 208	6.58 (7.336)	10.64 (9.305)
Ribavirin dose reduction, n=79, 189	12.43 (9.681)	10.99 (8.984)

12. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Levels of Peginterferon Dose Reductions in the DB Phase
Measure Description	The assigned dose in the DB Phase of peginterferon alfa-2a was 180 micrograms (µg). For peginterferon dose modification, downward adjustments in one-level increments were considered. The lowest dose of peginterferon alfa-2a that was allowed to be administered was 45 µg. When dose adjustment was required for moderate to severe adverse reactions (clinical and/or laboratory), an initial dose reduction to 135 µg was generally adequate. In some cases, a dose reduction to 90 µg or 45 µg was necessary. Dose increases toward the original dose were considered when the adverse reaction was resolved.
Time Frame	From Baseline up to Week 48 or Week 72 (for participants with Genotype 2/3) or up to Week 72 (for participants with Non-Genotype 2/3)
Safety Issue?	No

Analysis Population Description

ITT Population. One participant could have had more than one dose reduction.

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	253	506
Number of Participants With the Indicated Levels of Peginterferon Dose Reductions in the DB Phase [units: participants]		
<=25%	44	89
>25% to <=34%	33	35
>34% to <=50%	115	112
>50%	33	30

13. Secondary Outcome Measure:

Measure Title	Number of Participants Who Prematurely Discontinued Antiviral Therapy in the DB Phase
Measure Description	The following participants were considered to have discontinued antiviral therapy: participants who were lost to follow-up; participants who withdrew for any reason; participants who died; participants who otherwise did not complete their planned course of antiviral therapy for any reason. The planned duration of antiviral therapy was 48 weeks for participants with Non-Genotype 2/3 and 24 or 48 weeks for participants with Genotype 2/3.
Time Frame	From Baseline up to Week 48 or Week 72 (for participants with Genotype 2/3) or up to Week 72 (for participants with Non-Genotype 2/3)
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	253	506
Number of Participants Who Prematurely Discontinued Antiviral Therapy in the DB Phase [units: participants]	164	242

14. Secondary Outcome Measure:

Measure Title	Number of Participants Categorized as Responders (R) and Non-responders (NR) for SVR and RVR to Antiviral Therapy in the Indicated Variants of Interleukin 28B (IL28B) (or Interferon, Lambda 3)
Measure Description	There are two genetic variants (rs12979860 and rs8099917) mapping near IL28B associated with both interferon-induced SVR and spontaneous HCV clearance. IL28B genotype distribution by response to antiviral therapy (SVR/RVR responders: those who achieved SVR/RVR; SVR/RVR non-responders: those who did not achieve SVR/RVR) was assessed. The effect of genotype was tested by comparing participants that carried 2 copies of the IL28B favorable response allele versus the others (recessive model). Genotypes at rs12979860 were coded as: CC=1, CT or TT=0; rs8099917 was coded as TT=1, GT or GG=0.
Time Frame	From Baseline up to Week 48 or Week 72 (for participants with Genotype 2/3) or up to Week 72 (for participants with Non-Genotype 2/3)
Safety Issue?	No

Analysis Population Description

Pharmacogenetic (PGx) Sub-Population: participants enrolled in this study who provided written informed consent for PGx research with a blood sample for genotyping and who were successfully genotyped for at least one of the two genetic markers under study. Only those participants who were analyzed for SVR and RVR were considered.

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	105	205
Number of Participants Categorized as Responders (R) and Non-responders (NR) for SVR and RVR to Antiviral Therapy in the Indicated Variants of Interleukin 28B (IL28B) (or Interferon, Lambda 3) [units: participants]		
SVR, rs12979860 (CC), R; n=12, 50	10	28
SVR, rs12979860 (CC), NR; n=105, 205	24	58
SVR, rs12979860 (CT), R; n=12, 50	2	18
SVR, rs12979860 (CT), NR; n=105, 205	60	111
SVR, rs12979860 (TT), R; n=12, 50	0	4
SVR, rs12979860 (TT), NR; n=105, 205	21	36
SVR, rs8099917 (TT), R; n=12, 50	11	36
SVR, rs8099917 (TT), NR; n=105, 205	48	89
SVR, rs8099917 (GT), R; n=12, 50	1	13
SVR, rs8099917 (GT), NR; n=105, 205	51	99
SVR, rs8099917 (GG), R; n=12, 50	0	1
SVR, rs8099917 (GG), NR; n=105, 205	6	17
RVR, rs12979860 (CC), R; n=11, 33	6	21
RVR, rs12979860 (CC), NR; n=106, 222	28	65
RVR, rs12979860 (CT), R; n=11, 33	5	11

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
RVR, rs12979860 (CT), NR; n=106, 222	57	118
RVR, rs12979860 (TT), R; n=11, 33	0	1
RVR, rs12979860 (TT), NR; n=106, 222	21	39
RVR, rs8099917 (TT), R, n=11, 33	9	28
RVR, rs8099917 (TT), NR; n=106, 222	50	97
RVR, rs8099917 (GT), R; n=11, 33	2	5
RVR, rs8099917 (GT), NR; n=106, 222	50	107
RVR, rs8099917 (GG), R; n=11, 33	0	0
RVR, rs8099917 (GG), R; n=106, 222	6	18

15. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Shift From Baseline (BL) in Severity Grades for Clinical Chemistry Parameters (Calcium, Glucose [Glu.], Potassium [Pot.], and Sodium [Sod.]), Per Division of Acquired Immunodeficiency Syndrome (DAIDS)
Measure Description	Blood samples for the assessment of clinical chemistry parameters were taken at intervals throughout the study. Participants with the worst-case shift from BL during the DB Phase are reported, per severity grades by DAIDS, for levels of calcium (low=hypocalcemia; high=hypercalcemia), glu. (low=hypoglycemia; high=hyperglycemia), pot. (low=hypokalemia; high=hyperkalemia), and sod. (low=hyponatremia; high=hypernatremia). Per the DAIDS toxicity table, the grade ranges for each parameter are as follows: Grade (G) 1=mild; G2=moderate; G3=severe; G4=potentially life-threatening.
Time Frame	From Baseline up to Week 48 or Week 72 (for participants with Genotype 2/3) or up to Week 72 (for participants with Non-Genotype 2/3)
Safety Issue?	No

Analysis Population Description

Safety DB Population: all randomized participants who had received study drug in the DB Phase

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

	Description
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	252	506
Number of Participants With the Indicated Shift From Baseline (BL) in Severity Grades for Clinical Chemistry Parameters (Calcium, Glucose [Glu.], Potassium [Pot.], and Sodium [Sod.]), Per Division of Acquired Immunodeficiency Syndrome (DAIDS) [units: participants]		
Calcium (hypocalcemia), Any Grade Increase	184	374
Calcium (hypocalcemia), Increase to G1	140	246
Calcium (hypocalcemia), Increase to G2	42	122
Calcium (hypocalcemia), Increase to G3	2	4
Calcium (hypocalcemia), Increase to G4	0	2
Calcium (hypercalcemia), Any Grade Increase	2	1
Calcium (hypercalcemia), Increase to G1	1	1
Calcium (hypercalcemia), Increase to G2	1	0
Calcium (hypercalcemia), Increase to G3	0	0
Calcium (hypercalcemia), Increase to G4	0	0
Glu. (hypoglycemia), Any Grade Increase	31	90
Glu. (hypoglycemia), Increase to G1	17	45
Glu. (hypoglycemia), Increase to G2	10	31
Glu. (hypoglycemia), Increase to G3	4	9
Glu. (hypoglycemia), Increase to G4	0	5
Glu. (hyperglycemia), Any Grade Increase	128	277
Glu. (hyperglycemia), Increase to G1	31	68

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Glu. (hyperglycemia), Increase to G2	77	161
Glu. (hyperglycemia), Increase to G3	19	44
Glu. (hyperglycemia), Increase to G4	1	4
Pot. (hyperkalemia), Any Grade Increase	3	15
Pot. (hyperkalemia), Increase to G1	2	7
Pot. (hyperkalemia), Increase to G2	1	3
Pot. (hyperkalemia), Increase to G3	0	2
Pot. (hyperkalemia), Increase to G4	0	3
Pot. (hypokalemia), Any Grade Increase	53	74
Pot. (hypokalemia), Increase to G1	48	66
Pot. (hypokalemia), Increase to G2	5	6
Pot. (hypokalemia), Increase to G3	0	2
Pot. (hypokalemia), Increase to G4	0	0
Sod. (hypernatremia), Any Grade Increase	14	21
Sod. (hypernatremia), Increase to G1	14	20
Sod. (hypernatremia), Increase to G2	0	1
Sod. (hypernatremia), Increase to G3	0	0
Sod. (hypernatremia), Increase to G4	0	0
Sod. (hyponatremia), Any Grade Increase	72	128
Sod. (hyponatremia), Increase to G1	69	118
Sod. (hyponatremia), Increase to G2	3	8
Sod. (hyponatremia), Increase to G3	0	1
Sod. (hyponatremia), Increase to G4	0	1

16. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Shifts From BL in Severity Grades for for Hematology Parameters (Hemoglobin, Lymphocytes [Lym.], Total Neutrophils [Tot Neu.], and White Blood Cells [WBC]), Per DAIDS

Measure Description	Blood samples for the assessment of hematology parameters were taken at intervals throughout the study. Participants with the worst-case shift from BL during the DB Phase are reported, per severity grades by DAIDS, for levels of hemoglobin (low=anemia), lymphocytes (low=lymphocytopenia), total neutrophils (low=neutropenia), and white blood cells (low=leukocytopenia). Per the DAIDS toxicity table, grade ranges for each parameter are as follows: Grade (G) 1=mild; G2=moderate; G3=severe; G4=potentially life-threatening.
Time Frame	From Baseline up to Week 48 or Week 72 (for participants with Genotype 2/3) or up to Week 72 (for participants with Non-Genotype 2/3)
Safety Issue?	No

Analysis Population Description

Safety DB Population

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	252	506
Number of Participants With the Indicated Shifts From BL in Severity Grades for for Hematology Parameters (Hemoglobin, Lymphocytes [Lym.], Total Neutrophils [Tot Neu.], and White Blood Cells [WBC]), Per DAIDS [units: participants]		
Hemoglobin (anemia), Any Grade Increase	161	361
Hemoglobin (anemia), Increase to G1	46	112
Hemoglobin (anemia), Increase to G2	64	129
Hemoglobin (anemia), Increase to G3	48	114
Hemoglobin (anemia), Increase to G4	3	6
Lym. (lymphocytopenia), Any Grade Increase	136	346

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Lym. (lymphocytopenia), Increase to G1	16	43
Lym. (lymphocytopenia), Increase to G2	38	80
Lym. (lymphocytopenia), Increase to G3	48	109
Lym. (lymphocytopenia), Increase to G4	34	114
Tot Neu. (neutropenia), Any Grade Increase	208	394
Tot Neu. (neutropenia), Increase to G1	50	106
Tot Neu. (neutropenia), Increase to G2	53	113
Tot Neu. (neutropenia), Increase to G3	73	128
Tot Neu. (neutropenia), Increase to G4	32	47
WBC (leukocytopenia), Any Grade Increase	191	391
WBC (leukocytopenia), Increase to G1	56	113
WBC (leukocytopenia), Increase to G2	69	145
WBC (leukocytopenia), Increase to G3	58	110
WBC (leukocytopenia), Increase to G4	8	23

17. Secondary Outcome Measure:

Measure Title	Number of Participants in the Indicated Categories for Cataract Event During the DB Phase, Per Clinical Events Committee (CEC) Adjudication
Measure Description	Ophthalmic (pertaining to eye) assessments were performed during the study. A cataract event is defined as an event ascertained to be a cataract (opacity or cloudiness of the lens of the eye, causing impairment of vision) by at least one of the CEC members (comprised of expert ophthalmologists who provided objective medical review of the blinded ophthalmic data). Per the CEC, cataract events were categorized as: (1) Cataract Progression (CP; progression of cataracts present at BL); and (2) Incident Cataract (IC; development of new cataracts). One eye=unilateral; both eyes=bilateral.
Time Frame	From Baseline up to Week 48 or Week 72 (for participants with Genotype 2/3) or up to Week 72 (for participants with Non-Genotype 2/3)
Safety Issue?	No

Analysis Population Description
Safety DB Population

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	252	506
Number of Participants in the Indicated Categories for Cataract Event During the DB Phase, Per Clinical Events Committee (CEC) Adjudication [units: participants]		
Unilateral CP, Genotype 2/3	0	1
Unilateral CP, Non-genotype 2/3	4	6
Bilateral CP, Genotype 2/3	3	1
Bilateral CP, Non-genotype 2/3	1	7
Unilateral IP, Genotype 2/3	1	4
Unilateral IP, Non-genotype 2/3	1	6
Bilateral IP, Genotype 2/3	3	1
Bilateral IP, Non-genotype 2/3	3	10

18. Secondary Outcome Measure:

Measure Title	Number of Participants Assessed as Normal and Abnormal (Clinically Significant [CS] and Not Clinically Significant [NCS]) for 12-lead Electrocardiogram (ECG) at the Indicated Time Points During the DB Phase

Measure Description	Duplicate 12-lead ECGs were required at Screening/BL, Antiviral BL, and at 12 weekly intervals during the study. The number of participants with an ECG status of normal, abnormal, CS, or NCS, as determined by the Investigator, was reported. Normal, all ECG parameters within accepted normal ranges. Abnormal, ECG finding(s) outside of normal ranges. CS, ECG with a CS abnormality that meets exclusion criteria. NCS, ECG with an abnormality not CS or meeting exclusion criteria, per Investigator, based on reasonable standards of clinical judgment.
Time Frame	DB Phase: Antiviral BL (up to Week 10); End of Treatment (up to Week 52); and 24-week FU (up to Week 72)
Safety Issue?	No

Analysis Population Description

Safety DB Population. Only those participants contributing data at the indicated time points were analyzed.

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	252	505
Number of Participants Assessed as Normal and Abnormal (Clinically Significant [CS] and Not Clinically Significant [NCS]) for 12-lead Electrocardiogram (ECG) at the Indicated Time Points During the DB Phase [units: participants]		
Antiviral BL, Normal, n=232, 478	147	332
Antiviral BL, Abnormal - NCS, n=232, 478	63	103
Antiviral BL, Abnormal - CS, n=232, 478	22	43
End of Treatment, Normal, n=218, 428	134	291
End of Treatment, Abnormal - NCS, n=218, 428	62	103
End of Treatment, Abnormal - CS, n=218, 428	22	34

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
24-week FU, Normal, n=194, 383	123	238
24-week FU, Abnormal - NCS, n=194, 383	49	107
24-week FU, Abnormal - CS, n=194, 383	22	38
Worst ECG post-BL, Normal, n=252, 505	113	233
Worst ECG post-BL, Abnormal - NCS, n=252, 505	91	171
Worst ECG post-BL, Abnormal - CS, n=252, 505	48	101

19. Secondary Outcome Measure:

Measure Title	Number of Participants With CS and NCS Change From Baseline for 12-lead ECG at the Indicated Time Points During the DB Phase
Measure Description	Duplicate 12-lead ECGs were required at Screening/BL, Antiviral BL, and at 12 weekly intervals during the study. The number of participants with a CS and a NCS change from baseline in ECG status, as determined by the Investigator, was reported. CS, ECG with a CS abnormality that meets exclusion criteria. NCS, ECG with an abnormality not CS or meeting exclusion criteria, per Investigator, based on reasonable standards of clinical judgment. "Not applicable" indicates that information was not provided by the investigator on whether the change from baseline ECG was CS or NCS.
Time Frame	End of Treatment (up to Week 52); and 24-week FU (up to Week 72)
Safety Issue?	No

Analysis Population Description

Safety DB Population. Only those participants contributing data at the indicated time points were analyzed.

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	218	428
Number of Participants With CS and NCS Change From Baseline for 12-lead ECG at the Indicated Time Points During the DB Phase [units: participants]		
End of Treatment, CS change from BL, n=218, 428	0	7
End of Treatment, NCS change from BL, n=218, 428	218	420
End of Treatment, Not applicable, n=218, 428	0	1
24-week FU, CS change from BL, n=194, 383	1	4
24-week FU, NCS change from BL, n=194, 383	193	379

20. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at the Indicated Time Points During the DB Phase
Measure Description	Participant's blood pressure was measured at the indicated time points during the study. Systolic blood pressure is a measure of blood pressure while the heart is beating. Diastolic blood pressure is a measure of blood pressure while the heart is relaxed. Mean change from Baseline was calculated as the value at the indicated time points minus the value at Baseline.
Time Frame	DB Phase: Baseline; Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24, 28, 32, 36, 40, and 44; End of Treatment (up to Week 48); 4-week Follow-up (FU) (up to Week 52); 12-week FU (up to Week 60); and 24-week FU (up to Week 72)
Safety Issue?	No

Analysis Population Description

Safety DB Population. Only those participants contributing data at the indicated time points were analyzed.

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

	Description
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	246	494
Mean Change From Baseline in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at the Indicated Time Points During the DB Phase [units: Millimeters of mercury (mmHg)] Mean (Standard Deviation)		
SBP, Week 1, n=246, 491	-3.00 (13.541)	-2.36 (12.296)
SBP, Week 2, n=242, 494	-3.25 (13.800)	-3.74 (13.122)
SBP, Week 4, n=228, 485	-3.75 (13.781)	-3.91 (13.780)
SBP, Week 6, n=206, 471	-3.36 (14.405)	-3.85 (14.624)
SBP, Week 8, n=190, 472	-2.72 (14.073)	-4.33 (14.401)
SBP, Week 12, n=175, 452	-2.16 (15.297)	-4.30 (14.377)
SBP, Week 16, n=143, 403	-3.16 (15.426)	-4.59 (13.579)
SBP, Week 20, n=133, 374	-2.50 (14.387)	-4.12 (14.908)
SBP, Week 24, n=99, 263	-1.97 (14.820)	-3.94 (14.917)
SBP, Week 28, n=74, 211	-0.69 (14.663)	-4.99 (14.557)
SBP, Week 32, n=67, 197	-1.46 (13.904)	-5.61 (13.523)
SBP, Week 36, n=62, 186	-1.31 (13.803)	-4.40 (14.842)
SBP, Week 40, n=59, 173	0.10 (13.605)	-4.31 (13.941)
SBP, Week 44, n=59, 167	0.56 (11.689)	-4.54 (13.794)
SBP, End of Treatment, n=238, 468	-2.03 (13.259)	-3.98 (15.318)
SBP, 4-week FU, n=221, 426	-1.14 (14.095)	-1.65 (15.122)
SBP, 12-week FU, n=207, 432	-0.11 (14.113)	-0.86 (14.806)
SBP, 24-week FU, n=203, 398	1.10 (14.545)	0.25 (14.518)

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
DBP, Week 1, n=246, 491	-1.43 (9.235)	-1.37 (8.224)
DBP, Week 2, n=242, 493	-1.55 (9.217)	-1.86 (8.946)
DBP, Week 4, n=228, 485	-1.84 (9.726)	-2.72 (9.467)
DBP, Week 6, n=206, 471	-2.16 (8.939)	-2.95 (9.859)
DBP, Week 8, n=190, 472	-1.24 (9.517)	-2.68 (9.901)
DBP, Week 12, n=175, 452	-1.31 (8.781)	-3.23 (10.025)
DBP, Week 16, n=143, 403	-1.54 (9.684)	-3.31 (9.899)
DBP, Week 20, n=133, 374	-0.93 (10.582)	-3.08 (9.606)
DBP, Week 24, n=99, 263	-1.66 (10.207)	-3.54 (9.313)
DBP, Week 28, n=74, 211	-1.23 (9.538)	-3.42 (10.502)
DBP, Week 32, n=67, 197	-0.54 (10.445)	-3.76 (9.527)
DBP, Week 36, n=62, 186	-0.74 (9.559)	-3.59 (9.211)
DBP, Week 40, n=59, 173	0.34 (9.343)	-3.32 (9.517)
DBP, Week 44, n=59, 167	0.92 (9.033)	-3.77 (10.134)
DBP, End of Treatment, n=238, 468	-1.55 (9.174)	-3.59 (10.254)
DBP, 4-week FU, n=221, 426	-0.83 (9.102)	-2.20 (9.824)
DBP, 12-week FU, n=207, 432	-0.78 (10.253)	-1.76 (9.903)
DBP, 24-week FU, n=203, 398	0.03 (9.814)	-1.61 (9.339)

21. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Heart Rate at the Indicated Time Points During the DB Phase
Measure Description	Heart rate was measured in participants at the indicated time points. Mean change from Baseline was calculated as the value at the indicated time points minus the value at Baseline.
Time Frame	DB Phase: Baseline; Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24, 28, 32, 36, 40, and 44; End of Treatment (up to Week 48); 4-week Follow-up (FU) (up to Week 52); 12-week FU (up to Week 60); and 24-week FU (up to Week 72)
Safety Issue?	No

Analysis Population Description

Safety DB Population. Only those participants contributing data at the indicated time points were analyzed.

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	244	490
Mean Change From Baseline in Heart Rate at the Indicated Time Points During the DB Phase [units: beats per minute] Mean (Standard Deviation)		
Week 1, n=244, 490	1.16 (8.358)	-0.43 (8.629)
Week 2, n=242, 490	1.89 (8.510)	0.78 (9.644)
Week 4, n=227, 483	2.47 (9.464)	1.50 (9.739)
Week 6, n=205, 470	3.23 (9.158)	1.19 (8.708)
Week 8, n=190, 472	2.91 (9.751)	1.78 (9.227)
Week 12, n=174, 450	4.28 (10.188)	2.02 (9.539)
Week 16, n=143, 403	5.87 (9.975)	2.38 (10.419)
Week 20, n=132, 371	5.73 (9.688)	2.10 (9.530)
Week 24, n=99, 262	3.77 (9.912)	2.03 (9.399)
Week 28, n=74, 211	2.72 (10.038)	1.64 (10.328)
Week 32, n=67, 196	4.28 (8.281)	1.62 (9.676)
Week 36, n=62, 186	5.42 (10.109)	2.11 (10.205)
Week 40, n=59, 171	4.83 (8.919)	0.78 (9.895)
Week 44, n=59, 165	5.53 (11.005)	1.16 (8.846)

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
End of Treatment, n=237, 467	4.01 (10.606)	2.89 (11.134)
4-week FU, n=220, 422	4.27 (10.432)	2.11 (10.113)
12-week FU, n=206, 429	1.73 (9.707)	0.74 (9.955)
24-week FU, n=202, 395	0.14 (9.803)	-1.90 (9.176)

22. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Weight at the Indicated Time Points During the DB Phase
Measure Description	The weight of participants was recorded at the indicated time points. Mean change from Baseline was calculated as the value at the indicated time points minus the value at Baseline.
Time Frame	DB Phase: Baseline; Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24, 28, 32, 36, 40, and 44; End of Treatment (up to Week 48); 4-week Follow-up (FU) (up to Week 52); 12-week FU (up to Week 60); and 24-week FU (up to Week 72)
Safety Issue?	No

Analysis Population Description

Safety DB Population. Only those participants contributing data at the indicated time points were analyzed.

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	248	495
Mean Change From Baseline in Weight at the Indicated Time Points During the DB Phase [units: Kilograms (kg)] Mean (Standard Deviation)		

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Week 1, n=248, 492	-0.65 (2.201)	-0.68 (2.062)
Week 2, n=244, 495	-0.88 (1.983)	-1.06 (2.809)
Week 4, n=229, 488	-1.30 (2.374)	-1.30 (2.488)
Week 6, n=207, 476	-1.42 (2.464)	-1.68 (2.652)
Week 8, n=191, 473	-1.89 (2.793)	-2.11 (2.810)
Week 12, n=175, 453	-2.18 (2.985)	-2.83 (3.440)
Week 16, n=145, 406	-2.37 (3.247)	-3.32 (3.798)
Week 20, n=134, 378	-3.08 (3.684)	-3.99 (4.040)
Week 24, n=99, 265	-4.04 (4.148)	-4.75 (4.175)
Week 28, n=74, 212	-4.57 (4.749)	-5.09 (5.016)
Week 32, n=67, 200	-4.50 (4.397)	-5.52 (5.369)
Week 36, n=63, 188	-4.54 (4.739)	-5.39 (7.476)
Week 40, n=59, 174	-4.99 (4.612)	-5.87 (5.571)
Week 44, n=59, 168	-4.79 (5.475)	-5.89 (5.661)
End of Treatment, n=240, 470	-3.28 (4.361)	-4.69 (5.180)
4-week FU, n=223, 425	-2.78 (4.318)	-3.84 (6.381)
12-week FU, n=210, 434	-1.98 (4.088)	-2.99 (5.999)
24-week FU, n=205, 401	-1.36 (4.568)	-1.51 (7.683)

23. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Body Mass Index (BMI) at the Indicated Time Points During the DB Phase
Measure Description	The BMI for participants was calculated at the indicated time points as body weight in kilograms divided by height in meters squared. Mean change from Baseline was calculated as the value at the indicated time points minus the value at Baseline.
Time Frame	DB Phase: Baseline; Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24, 28, 32, 36, 40, and 44; End of Treatment (up to Week 48); 4-week Follow-up (FU) (up to Week 52); 12-week FU (up to Week 60); and 24-week FU (up to Week 72)
Safety Issue?	No

Analysis Population Description

Safety DB Population. Only those participants contributing data at the indicated time points were analyzed.

Reporting Groups

	Description
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Measured Values

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Number of Participants Analyzed	248	493
Mean Change From Baseline in Body Mass Index (BMI) at the Indicated Time Points During the DB Phase [units: Kilograms per meters squared (kg/m^2)] Mean (Standard Deviation)		
Week 1, n=248, 490	-0.23 (0.771)	-0.23 (0.713)
Week 2, n=244, 493	-0.31 (0.691)	-0.36 (0.921)
Week 4, n=229, 486	-0.46 (0.823)	-0.45 (0.855)
Week 6, n=207, 474	-0.50 (0.871)	-0.58 (0.893)
Week 8, n=191, 471	-0.66 (0.967)	-0.73 (0.955)
Week 12, n=175, 451	-0.77 (1.055)	-0.97 (1.167)
Week 16, n=145, 404	-0.85 (1.158)	-1.15 (1.285)
Week 20, n=134, 376	-1.11 (1.324)	-1.39 (1.377)
Week 24, n=99, 264	-1.46 (1.509)	-1.66 (1.624)
Week 28, n=74, 211	-1.67 (1.731)	-1.79 (1.733)
Week 32, n=67, 199	-1.64 (1.586)	-1.94 (1.844)
Week 36, n=63, 187	-1.65 (1.703)	-1.89 (2.651)
Week 40, n=59, 173	-1.81 (1.671)	-2.09 (1.953)

	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
Week 44, n=59, 167	-1.73 (2.007)	-2.09 (1.942)
End of Treatment, n=240, 468	-1.16 (1.553)	-1.64 (1.783)
4-week FU, n=223, 423	-0.98 (1.519)	-1.35 (2.306)
12-week FU, n=210, 432	-0.70 (1.434)	-1.06 (2.055)
24-week FU, n=205, 399	-0.47 (1.544)	-0.53 (2.736)

Reported Adverse Events

Time Frame	Adverse events (AEs) are reported for the Double-blind (DB) on-treatment + 30 days period (up to Study Week 52).
Additional Description	In the study, AEs were collected during the Open-Label (OL) Pre-Antiviral Treatment Phase and the Double-Blind (DB) Phase, which included antiviral therapy and a 6-month post-therapy follow-up. Data for SAEs and AEs are presented for the Safety Population, comprised of all randomized participants who received the study drug.

Reporting Groups

	Description
Eltrombopag: OL Phase	Participants with a platelet count of <75 giga (10^9) cells per liter (Gi/L) initially received eltrombopag 25 milligrams (mg) once daily (QD) for 2 weeks. After 2 weeks, if the platelet count was <100 Gi/L, participants underwent dose escalation to 50 mg QD for 2 weeks. If platelet counts still remained <100 Gi/L, further dose escalations to 75 mg QD (up to 2 weeks) and 100 mg QD (up to a maximum of 3 weeks) were allowed. Participants who achieved platelet counts >=100 Gi/L during the OL Phase (maximum of up to 9 weeks) were eligible to enter the Double-blind (DB) Antiviral Treatment Phase, whereas those who failed to reach platelet counts >=100 Gi/L were discontinued from eltrombopag and had to attend the post-treatment follow-up visits.
Placebo+Antiviral Therapy: DB Phase	Participants completing the OL Phase were administered matching placebo tablets QD in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).
Eltrombopag+Antiviral Therapy: DB Phase	Participants completing the OL Phase continued on the same dose of eltrombopag received in the OL Phase (dose that effectively raised platelets to >=100 Gi/L) in combination with antiviral therapy (peginterferon alfa-2b and ribavirin) for a duration of either 24 or 48 weeks (for participants with Genotype 2/3) or 48 weeks (for participants with Non-Genotype 2/3).

Serious Adverse Events

	Eltrombopag: OL Phase	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	9/805 (1.12%)	49/252 (19.44%)	119/506 (23.52%)
Blood and lymphatic system disorders			
Anemia [A] †	0/805 (0%)	2/252 (0.79%)	5/506 (0.99%)
Anemia hemolytic autoimmune [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Febrile neutropenia [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Leukopenia [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Lymphadenitis [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Neutropenia [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Pancytopenia [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Splenomegaly [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Thrombocytopenia [A] †	0/805 (0%)	1/252 (0.4%)	5/506 (0.99%)
Cardiac disorders			
Angina pectoris [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Angina unstable [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Atrial fibrillation [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Cardiac arrest [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Cardio-respiratory arrest [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Coronary artery disease [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Myocardial infarction [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Ear and labyrinth disorders			
Vertigo [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Eye disorders			

	Eltrombopag: OL Phase	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Cataract [A] †	0/805 (0%)	1/252 (0.4%)	9/506 (1.78%)
Glaucoma [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Retinal hemorrhage [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Retinal vein thrombosis [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Visual acuity reduced [A] †	0/805 (0%)	1/252 (0.4%)	2/506 (0.4%)
Gastrointestinal disorders			
Abdominal adhesions [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Abdominal pain [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Abdominal pain upper [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Anal fissure [A] †	0/805 (0%)	0/252 (0%)	2/506 (0.4%)
Ascites [A] †	0/805 (0%)	2/252 (0.79%)	6/506 (1.19%)
Caecitis [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Diarrhea [A] †	0/805 (0%)	0/252 (0%)	2/506 (0.4%)
Duodenal ulcer [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Esophageal varices hemorrhage [A] †	0/805 (0%)	4/252 (1.59%)	4/506 (0.79%)
Gastric ulcer [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Gastric varices hemorrhage [A] †	1/805 (0.12%)	0/252 (0%)	0/506 (0%)
Gastritis erosive [A] †	0/805 (0%)	1/252 (0.4%)	1/506 (0.2%)
Gastrointestinal hemorrhage [A] †	0/805 (0%)	0/252 (0%)	5/506 (0.99%)
Hematemesis [A] †	0/805 (0%)	0/252 (0%)	2/506 (0.4%)
Hemorrhoids [A] †	0/805 (0%)	0/252 (0%)	2/506 (0.4%)

	Eltrombopag: OL Phase	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Mechanical ileus [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Mesenteric vein thrombosis [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Nausea [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Pancreatitis [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Rectal hemorrhage [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Upper gastrointestinal hemorrhage [A] †	0/805 (0%)	1/252 (0.4%)	3/506 (0.59%)
Varices esophageal [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Vomiting [A] †	0/805 (0%)	1/252 (0.4%)	2/506 (0.4%)
General disorders			
Asthenia [A] †	0/805 (0%)	1/252 (0.4%)	1/506 (0.2%)
Chest pain [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Death [A] †	0/805 (0%)	1/252 (0.4%)	1/506 (0.2%)
Edema peripheral [A] †	0/805 (0%)	1/252 (0.4%)	1/506 (0.2%)
Generalized edema [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Induration [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Malaise [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Medical device complication [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Multi-organ disorder [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Multi-organ failure [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Non-cardiac chest pain [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Pyrexia [A] †	0/805 (0%)	1/252 (0.4%)	2/506 (0.4%)

	Eltrombopag: OL Phase	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Sudden death [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Hepatobiliary disorders			
Autoimmune hepatitis [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Cholecystitis [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Cholecystitis acute [A] †	0/805 (0%)	1/252 (0.4%)	1/506 (0.2%)
Cholelithiasis [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Hepatic cirrhosis [A] †	0/805 (0%)	1/252 (0.4%)	2/506 (0.4%)
Hepatic failure [A] †	0/805 (0%)	0/252 (0%)	3/506 (0.59%)
Hepatitis [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Hepatorenal syndrome [A] †	1/805 (0.12%)	0/252 (0%)	1/506 (0.2%)
Hepatorenal syndrome [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Jaundice [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Jaundice cholestatic [A] †	0/805 (0%)	0/252 (0%)	2/506 (0.4%)
Portal hypertension [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Portal vein thrombosis [A] †	0/805 (0%)	0/252 (0%)	2/506 (0.4%)
Immune system disorders			
Amyloidosis [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Infections and infestations			
Abdominal sepsis [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Abdominal wall abscess [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Abscess limb [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Actinomycotic pulmonary infection [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)

	Eltrombopag: OL Phase	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Anal abscess [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Anogenital warts [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Appendicitis [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Arthritis bacterial [A] †	1/805 (0.12%)	0/252 (0%)	0/506 (0%)
Brain abscess [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Bronchitis [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Campylobacter intestinal infection [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Cellulitis [A] †	0/805 (0%)	2/252 (0.79%)	2/506 (0.4%)
Clostridial infection [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Empyema [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Lobar pneumonia [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Peritoneal infection [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Peritonitis bacterial [A] †	0/805 (0%)	0/252 (0%)	2/506 (0.4%)
Pneumonia [A] †	1/805 (0.12%)	4/252 (1.59%)	7/506 (1.38%)
Pneumonia influenzal [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Postoperative abscess [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Pulmonary tuberculosis [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Pyelonephritis acute [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Salmonella bacteremia [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Sepsis [A] †	0/805 (0%)	0/252 (0%)	4/506 (0.79%)
Tonsillitis [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)

	Eltrombopag: OL Phase	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Urinary tract infection [A] †	1/805 (0.12%)	2/252 (0.79%)	1/506 (0.2%)
Urosepsis [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Viral pharyngitis [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Injury, poisoning and procedural complications			
Ankle fracture [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Cataract traumatic [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Pubis fracture [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Radius fracture [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Spinal compression fracture [A] †	1/805 (0.12%)	0/252 (0%)	0/506 (0%)
Spinal fracture [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Tibia fracture [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Investigations			
Blood creatinine increased [A] †	1/805 (0.12%)	0/252 (0%)	0/506 (0%)
Blood potassium decreased [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Metabolism and nutrition disorders			
Decreased appetite [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Diabetes mellitus [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Hyperglycemia [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Hyperkalemia [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Hypoglycemia [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Musculoskeletal and connective tissue disorders			
Arthralgia [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)

	Eltrombopag: OL Phase	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Back pain [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign hepatic neoplasm [A] †	0/805 (0%)	0/252 (0%)	2/506 (0.4%)
Bile duct cancer [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Gastric cancer [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Hepatic neoplasm [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Hepatic neoplasm malignant [A] †	1/805 (0.12%)	7/252 (2.78%)	22/506 (4.35%)
Lung squamous cell carcinoma stage unspecified [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Nervous system disorders			
Cerebrovascular accident [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Coma [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Coma hepatic [A] †	0/805 (0%)	0/252 (0%)	2/506 (0.4%)
Encephalopathy [A] †	0/805 (0%)	1/252 (0.4%)	1/506 (0.2%)
Hepatic encephalopathy [A] †	0/805 (0%)	1/252 (0.4%)	9/506 (1.78%)
Osmotic demyelination syndrome [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Syncope [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Psychiatric disorders			
Abnormal behavior [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Affect lability [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Confusional state [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Delirium [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)

	Eltrombopag: OL Phase	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Delirium tremens [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Depressed mood [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Depression [A] †	0/805 (0%)	2/252 (0.79%)	2/506 (0.4%)
Insomnia [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Mental status changes [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Suicidal ideation [A] †	1/805 (0.12%)	0/252 (0%)	2/506 (0.4%)
Suicide attempt [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Renal and urinary disorders			
Acute prerenal failure [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Nephrolithiasis [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Renal failure [A] †	0/805 (0%)	0/252 (0%)	2/506 (0.4%)
Renal failure acute [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Asthma [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Dyspnea [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Dyspnea exertional [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Epistaxis [A] †	0/805 (0%)	2/252 (0.79%)	0/506 (0%)
Oropharyngeal pain [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Pharyngeal ulceration [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Pneumonia aspiration [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Pneumonitis [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)

	Eltrombopag: OL Phase	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Pulmonary embolism [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Respiratory failure [A] †	0/805 (0%)	0/252 (0%)	2/506 (0.4%)
Skin and subcutaneous tissue disorders			
Intertrigo [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Vascular disorders			
Aortic stenosis [A] †	0/805 (0%)	0/252 (0%)	2/506 (0.4%)
Deep vein thrombosis [A] †	0/805 (0%)	0/252 (0%)	2/506 (0.4%)
Femoral artery occlusion [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)
Hypotension [A] †	0/805 (0%)	0/252 (0%)	2/506 (0.4%)
Phlebitis [A] †	0/805 (0%)	1/252 (0.4%)	0/506 (0%)
Vasculitis [A] †	0/805 (0%)	0/252 (0%)	1/506 (0.2%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA

Other Adverse Events

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

	Eltrombopag: OL Phase	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/805 (0%)	226/252 (89.68%)	459/506 (90.71%)
Blood and lymphatic system disorders			
Anemia [A] †	0/805 (0%)	90/252 (35.71%)	200/506 (39.53%)
Leukopenia [A] †	0/805 (0%)	32/252 (12.7%)	57/506 (11.26%)
Neutropenia [A] †	0/805 (0%)	83/252 (32.94%)	139/506 (27.47%)
Thrombocytopenia [A] †	0/805 (0%)	83/252 (32.94%)	61/506 (12.06%)

	Eltrombopag: OL Phase	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Gastrointestinal disorders			
Abdominal pain [A] †	0/805 (0%)	10/252 (3.97%)	31/506 (6.13%)
Abdominal pain upper [A] †	0/805 (0%)	13/252 (5.16%)	28/506 (5.53%)
Ascites [A] †	0/805 (0%)	6/252 (2.38%)	28/506 (5.53%)
Diarrhea [A] †	0/805 (0%)	24/252 (9.52%)	92/506 (18.18%)
Nausea [A] †	0/805 (0%)	38/252 (15.08%)	92/506 (18.18%)
Vomiting [A] †	0/805 (0%)	18/252 (7.14%)	41/506 (8.1%)
General disorders			
Asthenia [A] †	0/805 (0%)	28/252 (11.11%)	86/506 (17%)
Chills [A] †	0/805 (0%)	32/252 (12.7%)	72/506 (14.23%)
Edema peripheral [A] †	0/805 (0%)	3/252 (1.19%)	36/506 (7.11%)
Fatigue [A] †	0/805 (0%)	53/252 (21.03%)	124/506 (24.51%)
Influenza like illness [A] †	0/805 (0%)	36/252 (14.29%)	100/506 (19.76%)
Injection site erythema [A] †	0/805 (0%)	14/252 (5.56%)	22/506 (4.35%)
Irritability [A] †	0/805 (0%)	11/252 (4.37%)	34/506 (6.72%)
Pyrexia [A] †	0/805 (0%)	60/252 (23.81%)	141/506 (27.87%)
Hepatobiliary disorders			
Hyperbilirubinemia [A] †	0/805 (0%)	11/252 (4.37%)	42/506 (8.3%)
Infections and infestations			
Urinary tract infection [A] †	0/805 (0%)	13/252 (5.16%)	29/506 (5.73%)
Investigations			
Blood bilirubin increased [A] †	0/805 (0%)	7/252 (2.78%)	36/506 (7.11%)

	Eltrombopag: OL Phase	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Hemoglobin decreased [A] †	0/805 (0%)	16/252 (6.35%)	34/506 (6.72%)
Platelet count decreased [A] †	0/805 (0%)	14/252 (5.56%)	27/506 (5.34%)
Weight decreased [A] †	0/805 (0%)	17/252 (6.75%)	49/506 (9.68%)
White blood cell count decreased [A] †	0/805 (0%)	18/252 (7.14%)	42/506 (8.3%)
Metabolism and nutrition disorders			
Decreased appetite [A] †	0/805 (0%)	36/252 (14.29%)	94/506 (18.58%)
Musculoskeletal and connective tissue disorders			
Arthralgia [A] †	0/805 (0%)	20/252 (7.94%)	33/506 (6.52%)
Muscle spasms [A] †	0/805 (0%)	14/252 (5.56%)	36/506 (7.11%)
Myalgia [A] †	0/805 (0%)	22/252 (8.73%)	51/506 (10.08%)
Nervous system disorders			
Dizziness [A] †	0/805 (0%)	13/252 (5.16%)	40/506 (7.91%)
Headache [A] †	0/805 (0%)	50/252 (19.84%)	95/506 (18.77%)
Psychiatric disorders			
Depression [A] †	0/805 (0%)	19/252 (7.54%)	47/506 (9.29%)
Insomnia [A] †	0/805 (0%)	27/252 (10.71%)	72/506 (14.23%)
Respiratory, thoracic and mediastinal disorders			
Cough [A] †	0/805 (0%)	26/252 (10.32%)	64/506 (12.65%)
Dyspnea [A] †	0/805 (0%)	10/252 (3.97%)	36/506 (7.11%)
Epistaxis [A] †	0/805 (0%)	16/252 (6.35%)	26/506 (5.14%)
Skin and subcutaneous tissue disorders			
Alopecia [A] †	0/805 (0%)	12/252 (4.76%)	50/506 (9.88%)

	Eltrombopag: OL Phase	Placebo+Antiviral Therapy: DB Phase	Eltrombopag+Antiviral Therapy: DB Phase
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Pruritus [A] †	0/805 (0%)	34/252 (13.49%)	71/506 (14.03%)
Rash [A] †	0/805 (0%)	10/252 (3.97%)	38/506 (7.51%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

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

GSK agreements may vary with individual investigators, but will not prohibit any investigator from publishing. GSK supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

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