Safety and Efficacy of Boceprevir in Previously Untreated Subjects With Chronic Hepatitis C Genotype 1 (Study P05216AM2) (COMPLETED) (SPRINT-2)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00705432

First received: June 24, 2008
Last updated: October 16, 2015
Last verified: October 2015
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Purpose

This study involves treatment with boceprevir or placebo in combination with PegIntron (PEG) + Ribavirin (RBV) (weight-based dosing [WBD]) in previously untreated adult participants with chronic hepatitis C (CHC) genotype 1. It is hypothesized that the addition of a third active anti- Hepatitis C Virus (anti-HCV) drug may lead to more rapid viral response than therapy with two drugs, and therefore, the addition of boceprevir to PegIntron plus ribavirin therapy after a 4-week lead-in period may allow for both increased rates of sustained virologic response (SVR) and shorter treatment durations (in some populations) than treatment with PegIntron plus ribavirin alone.

The study includes two separate cohorts, Cohort I (White participants) and Cohort II (Black participants). Participants from each cohort are assigned (randomized) to one of three study arms, all of which have a 4-week lead-in period with (PEG + RBV).

Condition	Intervention	Phase
Hepatitis C, Chronic	Biological: Peginterferon alfa-2b (PEG) Drug: Ribavirin (RBV) Drug: Placebo Drug: Boceprevir	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Phase 3, Safety and Efficacy Study of Boceprevir in Previously Untreated Subjects With Chronic Hepatitis C Genotype 1

Resource links provided by NLM:

MedlinePlus related topics: Hepatitis Hepatitis A Hepatitis C

Drug Information available for: Ribavirin Peginterferon Alfa-2b Boceprevir

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Sustained Virologic Response (SVR) Rate [Time Frame: At Follow-up Week (FW) 24] [Designated as safety issue: No]

  Previously untreated adults with CHC genotype 1 were treated with the assigned study medication. Participants who had undetectable plasma HCV-RNA at FW 24 had achieved SVR. SVR rate is the percent of participants achieving SVR. HCV-RNA was detected by a nucleic acid amplification test and the limit of detection for this assay is 9.3 IU/mL. If a participant was missing data at FW 24 after having had undetectable HCV-RNA at FW 12, the participant was to be considered to have SVR.

Secondary Outcome Measures:

- Sustained Virologic Response (SVR) Rate in Participants Treated With Study Drug (Boceprevir or Placebo) [Time Frame: At FW 24] [Designated as safety issue: No]

  Previously untreated adults with CHC genotype 1 were treated with the assigned study medication. Participants who had undetectable plasma HCV-RNA at FW 24 had achieved SVR. SVR rate was the percentage of participants treated with at least one dose of boceprevir or placebo who had achieved SVR. HCV-RNA in participant's plasma samples was detected by a nucleic acid amplification assay with a limit of detection of 9.3 IU/mL. If a participant was missing data at FW 24 after having had undetectable HCV-RNA at FW 12, the participant was to be considered to have a SVR.

- Number of Participants With Undetectable HCV-RNA at Follow-up Week 12 and at 72 Weeks After Randomization. [Time Frame: At FW 12 and at 72 weeks after randomization] [Designated as safety issue: No]

  Previously untreated adults with CHC genotype 1 were treated with the assigned study medication. The number of participants who had undetectable plasma HCV-RNA at FW 12, and 72 weeks after randomization are reported. HCV-RNA was detected by a nucleic acid amplification test and the limit of detection for this assay is 9.3 IU/mL.

- Number of Participants With Early Virologic Response (Undetectable HCV-RNA at Treatment Week 2, 4, 8, 12, 16, or 20) [Time Frame: At Treatment Week 2, 4, 8, 12, 16, or 20] [Designated as safety issue: No]

  Early virologic response was defined as undetectable HCV-RNA at in participants by treatment week 2, 4, 8, 12, 16, or 20. HCV-RNA in participant's plasma samples was detected by a nucleic acid amplification assay with a limit of detection of 9.3 IU/mL.

- Number of Participants With Early Virologic Response (Undetectable HCV-RNA at Treatment Week 4, 8, 12, 16, or 20) Who Achieved SVR [Time Frame: At Treatment Week 4, 8, 12, 16, 20] [Designated as safety issue: No]

  Participants with early virologic response were those who had undetectable HCV-RNA by treatment week 4, 8, 12, 16, or 20. Participants who had undetectable plasma HCV-RNA at FW 24 had SVR. The number of participants with early virologic response that also achieved SVR is reported. HCV-RNA in participant's plasma samples was detected by a nucleic acid amplification assay with a limit of detection of 9.3 IU/mL.

Enrollment:	1472
Study Start Date:	August 2008
Study Completion Date:	May 2010
Primary Completion Date:	May 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Placebo Comparator: 1. Placebo + PEG + RBV PegIntron (PEG) 1.5 µg/kg + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks (lead in treatment) followed by placebo + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.	Biological: Peginterferon alfa-2b (PEG) Peginterferon alfa-2b 1.5 µg/kg/week subcutaneously (SC) Other Names: • PegIntron • PEG • SCH 54031 Drug: Ribavirin (RBV)

	Ribavirin weight-based dosing (WBD) 600 mg/day to 1400 mg/day administered orally, divided twice daily (BID). Other Names: • Rebetol • RBV • SCH 18908 Drug: Placebo Placebo to boceprevir, 800 mg (4 x 200mg capsules) administered orally three times a day (TID).
Experimental: 2. Boceprevir + PEG + RBV - 24 Weeks (RGT) PEG 1.5 µg/kg + RBV (WBD) for 4 weeks (lead in treatment) followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 24 weeks. Participants were offered a response guided therapy (RGT) at treatment week 28. • At the Treatment Week 28 visit, participants whose HCV-RNA was undetectable from Treatment Weeks 8 to Treatment Week 24, will proceed to the 44-week follow-up. • At the Treatment Week 28 visit, participants with detectable HCV-RNA at Treatment Week 8 or at any subsequent assays will continue on therapy with placebo + PEG 1.5 µg/kg + RBV (WBD) for an additional 20 weeks, to complete a total of 48 weeks on treatment with 24 weeks post-treatment follow-up.	Biological: Peginterferon alfa-2b (PEG) Peginterferon alfa-2b 1.5 µg/kg/week subcutaneously (SC) Other Names: • PegIntron • PEG • SCH 54031 Drug: Ribavirin (RBV) Ribavirin weight-based dosing (WBD) 600 mg/day to 1400 mg/day administered orally, divided twice daily (BID). Other Names: • Rebetol • RBV • SCH 18908 Drug: Boceprevir Boceprevir, 800 mg (4 x 200 mg capsules) administered orally TID. Other Name: SCH 503034, Victrelis
Experimental: 3. Boceprevir + PEG + RBV - 44 Weeks PEG 1.5 µg/kg + RBV (WBD) for 4 weeks (lead in treatment) followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.	Biological: Peginterferon alfa-2b (PEG) Peginterferon alfa-2b 1.5 µg/kg/week subcutaneously (SC) Other Names: • PegIntron • PEG • SCH 54031 Drug: Ribavirin (RBV) Ribavirin weight-based dosing (WBD) 600 mg/day to 1400 mg/day administered orally, divided twice daily (BID). Other Names: • Rebetol • RBV • SCH 18908 Drug: Boceprevir Boceprevir, 800 mg (4 x 200 mg

	capsules) administered orally TID. Other Name: SCH 503034, Victrelis

Detailed Description:

Participants from Cohort I and Cohort II are assigned (randomized) to one of three study arms, all of which have a 4-week lead-in period with (PEG + RBV).

1. Control arm, participants are treated with (PEG + RBV + placebo) for 44 weeks after the lead-in.
2. Experimental arm with Response Guided Therapy (RGT) In this experimental arm, participants are treated with all three drugs (PEG + RBV + boceprevir) for 24 weeks after the lead-in. At treatment week 28, those participants with undetectable Hepatitis C Virus - ribonucleic acid (HCV-RNA) from week 8 (up to treatment week 24), will be considered to complete treatment, and will enter follow-up. Participants with detectable for HCV-RNA at week 8 or later will receive an additional 20 weeks of therapy with PegIntron and Ribavirin (PEG + RBV + placebo).
3. Experimental arm, participants are treated with all three drugs (PEG + RBV + Ribavirin) for 44 weeks after the lead-in.

All participants were followed up to 72 weeks following randomization.

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Participant must have previously documented CHC genotype 1 infection.
- Participant must have a liver biopsy with histology consistent with CHC and no other etiology.
- Participants with bridging fibrosis or cirrhosis must have an ultrasound within 6 months of the Screening Visit (or between Screening and Day 1) with no findings suspicious for hepatocellular carcinoma (HCC).
- Participant must be >=18 years of age.
- Participant must weigh between 40 kg and 125 kg.
- Participant and participant's partner(s) must each agree to use acceptable methods of contraception for at least 2 weeks prior to Day 1 and continue until at least 6 months after last dose of study drug, or longer if dictated by local regulations.
- Participants must be willing to give written informed consent.

Exclusion Criteria:

- Coinfection with the human immunodeficiency virus (HIV) or hepatitis B virus (HBsAg positive).
- Participants who received prior treatment for hepatitis C; other than herbal remedies, except those with known hepatotoxicity.
- Treatment with any investigational drug within 30 days of the randomization visit in this study.
- Participation in any other clinical trial within 30 days of randomization or intention to participate in another clinical trial during participation in this study.
- Evidence of decompensated liver disease including, but not limited to, a history or presence of clinical ascites, bleeding varices, or hepatic encephalopathy.
- Diabetic and/or hypertensive participants with clinically significant ocular examination findings: retinopathy, cotton wool spots, optic nerve disorder, retinal hemorrhage, or any other clinically significant abnormality.
- Pre-existing psychiatric condition(s).
- Clinical diagnosis of substance abuse of the specified drugs within the specified timeframes.
- Any known pre-existing medical condition that could interfere with the participant's participation in and completion of the study.
- Evidence of active or suspected malignancy, or a history of malignancy, within the last 5 years (except adequately treated carcinoma in situ and basal cell carcinoma of the skin). Participants under evaluation for malignancy are not eligible.
- Participants who are pregnant or nursing. Participants who intend to become pregnant during the study period. Male participants with partners who are, or intend to become, pregnant during the study period.
- Any other condition which, in the opinion of a physician, would make the participant unsuitable for enrollment or could interfere with the participant participating in and completing the study.
- Participants who are part of the site personnel directly involved with this study.
- Participants who are family members of the investigational study staff.
- Participants who had life-threatening serious adverse event (SAE) during screening period.
- Protocol-specified hematologic, biochemical, and serologic criteria: Hemoglobin <12 g/dL for females and <13 g/dL for males; Neutrophils

<1500/mm^3 (blacks: <1200/mm^3); Platelets <100,000/mm^3; Direct bilirubin >1.5 x upper limit of normal (ULN)

- Serum albumin < lower limit of normal (LLN)
- Thyroid-stimulating hormone (TSH) >1.2 x ULN or <0.8 x LLN of laboratory, with certain exceptions.
- Serum creatinine >ULN of the laboratory reference.
- Protocol-specified serum glucose concentrations.
- protocol-specified alpha fetoprotein levels.
- Prothrombin time/partial thromboplastin time (PT/PTT) values >10% above laboratory reference range.
- Anti-nuclear antibodies (ANA) >1:320.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

No Contacts or Locations Provided

More Information

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Ferrante SA, Chhatwal J, Brass CA, El Khoury AC, Poordad F, Bronowicki JP, Elbasha EH. Boceprevir for previously untreated patients with chronic hepatitis C Genotype 1 infection: a US-based cost-effectiveness modeling study. BMC Infect Dis. 2013 Apr 27;13:190. doi: 10.1186/1471-2334-13-190.

Poordad F, Bronowicki JP, Gordon SC, Zeuzem S, Jacobson IM, Sulkowski MS, Poynard T, Morgan TR, Molony C, Pedicone LD, Sings HL, Burroughs MH, Sniukiene V, Boparai N, Goteti VS, Brass CA, Albrecht JK, Bacon BR; SPRINT-2 and RESPOND-2 Investigators. Factors that predict response of patients with hepatitis C virus infection to boceprevir. Gastroenterology. 2012 Sep;143(3):608-18.e1-5. doi: 10.1053/j.gastro.2012.05.011. Epub 2012 May 21.

Poordad F, McCone J Jr, Bacon BR, Bruno S, Manns MP, Sulkowski MS, Jacobson IM, Reddy KR, Goodman ZD, Boparai N, DiNubile MJ, Sniukiene V, Brass CA, Albrecht JK, Bronowicki JP; SPRINT-2 Investigators. Boceprevir for untreated chronic HCV genotype 1 infection. N Engl J Med. 2011 Mar 31;364(13):1195-206. doi: 10.1056/NEJMoa1010494.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00705432 History of Changes
Obsolete Identifiers:	NCT00795431
Other Study ID Numbers:	P05216 EUDRACT # 2007-005508-42
Study First Received:	June 24, 2008
Results First Received:	May 13, 2011
Last Updated:	October 16, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Hepatitis	Virus Diseases
Hepatitis A	Interferon-alpha
Hepatitis C	Peginterferon alfa-2b
Hepatitis C, Chronic	Ribavirin
Hepatitis, Chronic	Anti-Infective Agents
Digestive System Diseases	Antimetabolites
Enterovirus Infections	Antiviral Agents
Flaviviridae Infections	Immunologic Factors
Hepatitis, Viral, Human	Molecular Mechanisms of Pharmacological Action
Liver Diseases	Pharmacologic Actions
Picornaviridae Infections	Physiological Effects of Drugs
RNA Virus Infections	Therapeutic Uses

ClinicalTrials.gov processed this record on May 08, 2016

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Safety and Efficacy of Boceprevir in Previously Untreated Subjects With Chronic Hepatitis C Genotype 1 (Study P05216AM2) (COMPLETED) (SPRINT-2)

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ClinicalTrials.gov Identifier:
NCT00705432

First received: June 24, 2008
Last updated: October 16, 2015
Last verified: October 2015
History of Changes

Results First Received: May 13, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Hepatitis C, Chronic
Interventions:	Biological: Peginterferon alfa-2b (PEG) Drug: Ribavirin (RBV) Drug: Placebo Drug: Boceprevir

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
1472 participants were enrolled in this study.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
373 participants were screened but not randomized. 1099 participants were randomized. Only 1097 received at least one dose of PegIntron (PEG) + Ribavirin (RBV) (lead-in treatment).

Reporting Groups

	Description
Cohort I - 1. Placebo + PEG + RBV	Cohort I (White participants) treated with PegIntron (PEG) 1.5 µg/kg + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by placebo + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Cohort I - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort I (White participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 24 weeks. Participants were offered a response guided therapy (RGT) at treatment week 28. • At the Treatment Week 28 visit, participants whose HCV-RNA was undetectable at Treatment Week 8 and at all subsequent assays (up to Treatment Week 24), will proceed to the 44-week follow-up. • At the Treatment Week 28 visit, participants with detectable HCV-RNA at Treatment Week 8 or at any subsequent assays will continue on therapy with placebo + PEG 1.5 µg/kg + RBV (WBD) for an additional 20 weeks, to complete a total of 48 weeks on treatment with 24 weeks post-treatment follow-up.
Cohort I - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort I (White participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Cohort II - 1. Placebo + PEG + RBV	Cohort II (Black participants) treated with PegIntron (PEG) 1.5 µg/kg + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by placebo + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Cohort II - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort II (Black participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 24 weeks. Participants were offered a response guided therapy (RGT) at treatment week 28. • At the Treatment Week 28 visit, participants whose HCV-RNA was undetectable at Treatment Week 8 and at all subsequent assays (up to Treatment Week 24), will proceed to the 44-week follow-up. • At the Treatment Week 28 visit, participants with detectable HCV-RNA at Treatment Week 8 or at any subsequent assays will continue on therapy with placebo + PEG 1.5 µg/kg + RBV (WBD) for an additional 20 weeks, to complete a total of 48 weeks on treatment with 24 weeks post-treatment follow-up.
Cohort II - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort II (Black participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.

Participant Flow for 2 periods

Period 1: Treatment Period

	Cohort I - 1. Placebo + PEG + RBV	Cohort I - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort I - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort II - 1. Placebo + PEG + RBV	Cohort II - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort II - 3. Boceprevir + PEG + RBV - 44 Weeks
STARTED	311	316	311	52	52	55
STARTED BOCEPREVIR/PLACEBO	297	303	299	47	47	55
COMPLETED	148	205	190	11	24	25
NOT COMPLETED	163	111	121	41	28	30
Adverse Event	45	37	51	12	8	9

Treatment failure	**92**	**42**	**33**	**25**	**13**	**14**
Non medical reason	**26**	**32**	**37**	**4**	**7**	**7**

Period 2: Follow-up Period (Upto Week 72)

	Cohort I - 1. Placebo + PEG + RBV	Cohort I - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort I - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort II - 1. Placebo + PEG + RBV	Cohort II - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort II - 3. Boceprevir + PEG + RBV - 44 Weeks
STARTED	**278**	**295**	**291**	**42**	**44**	**53**
COMPLETED	**207**	**252**	**266**	**28**	**38**	**46**
NOT COMPLETED	**71**	**43**	**25**	**14**	**6**	**7**
Adverse Event	**2**	**1**	**1**	**0**	**0**	**0**
Non medical reason	**69**	**42**	**24**	**14**	**6**	**7**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Cohort I - 1. Placebo + PEG + RBV	Cohort I (White participants) treated with PegIntron (PEG) 1.5 µg/kg + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by placebo + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Cohort I - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort I (White participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 24 weeks. Participants were offered a response guided therapy (RGT) at treatment week 28. • At the Treatment Week 28 visit, participants whose HCV-RNA was undetectable at Treatment Week 8 and at all subsequent assays (up to Treatment Week 24), will proceed to the 44-week follow-up. • At the Treatment Week 28 visit, participants with detectable HCV-RNA at Treatment Week 8 or at any subsequent assays will continue on therapy with placebo + PEG 1.5 µg/kg + RBV (WBD) for an additional 20 weeks, to complete a total of 48 weeks on treatment with 24 weeks post-treatment follow-up.
Cohort I - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort I (White participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Cohort II - 1. Placebo + PEG + RBV	Cohort II (Black participants) treated with PegIntron (PEG) 1.5 µg/kg + Ribavirin

	(RBV) (weight-based dosing [WBD]) for 4 weeks followed by placebo + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Cohort II - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort II (Black participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 24 weeks. Participants were offered a response guided therapy (RGT) at treatment week 28. • At the Treatment Week 28 visit, participants whose HCV-RNA was undetectable at Treatment Week 8 and at all subsequent assays (up to Treatment Week 24), will proceed to the 44-week follow-up. • At the Treatment Week 28 visit, participants with detectable HCV-RNA at Treatment Week 8 or at any subsequent assays will continue on therapy with placebo + PEG 1.5 µg/kg + RBV (WBD) for an additional 20 weeks, to complete a total of 48 weeks on treatment with 24 weeks post-treatment follow-up.
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Total	Total of all reporting groups

Baseline Measures

	Cohort I - 1. Placebo + PEG + RBV	Cohort I - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort I - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort II - 1. Placebo + PEG + RBV	Cohort II - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort II - 3. Boceprevir + PEG + RBV - 44 Weeks	Total
Number of Participants [units: participants]	**311**	**316**	**311**	**52**	**52**	**55**	**1097**
Age, Customized [units: participants]							
<40 years	**51**	**45**	**49**	**6**	**3**	**4**	**158**
>= 40 and <65 years	**246**	**261**	**255**	**45**	**47**	**51**	**905**
>=65 years	**14**	**10**	**7**	**1**	**2**	**0**	**34**
Gender [units: participants]							
Female	**140**	**116**	**123**	**17**	**23**	**22**	**441**
Male	**171**	**200**	**188**	**35**	**29**	**33**	**656**

Outcome Measures

Hide All Outcome Measures

1. Primary: Sustained Virologic Response (SVR) Rate [Time Frame: At Follow-up Week (FW) 24]

Measure Type	Primary

Measure Title	Sustained Virologic Response (SVR) Rate
Measure Description	Previously untreated adults with CHC genotype 1 were treated with the assigned study medication. Participants who had undetectable plasma HCV-RNA at FW 24 had achieved SVR. SVR rate is the percent of participants achieving SVR. HCV-RNA was detected by a nucleic acid amplification test and the limit of detection for this assay is 9.3 IU/mL. If a participant was missing data at FW 24 after having had undetectable HCV-RNA at FW 12, the participant was to be considered to have SVR.
Time Frame	At Follow-up Week (FW) 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS). All randomized participants who received at least one dose of any study medication (PEG, RBV or boceprevir).

Reporting Groups

	Description
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Cohort II - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort II (Black participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.

Measured Values

	Cohort I - 1. Placebo + PEG + RBV	Cohort I - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort I - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort II - 1. Placebo + PEG + RBV	Cohort II - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort II - 3. Boceprevir + PEG + RBV - 44 Weeks
Number of Participants Analyzed [units: participants]	**311**	**316**	**311**	**52**	**52**	**55**
Sustained Virologic Response (SVR) Rate [units: Percentage of participants]	**40.2**	**66.8**	**68.5**	**23.1**	**42.3**	**52.7**

Statistical Analysis 1 for Sustained Virologic Response (SVR) Rate

Groups [1]	Cohort I - 1. Placebo + PEG + RBV vs. Cohort I - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)
Method [2]	Cochran-Mantel Haenszel Chi-square test
P Value [3]	<0.0001
The difference in SVR [4]	26.6
95% Confidence Interval	19.1 to 34.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Adjustments were made for for baseline stratification factors: viral load (>400,000 vs. ≤400,000 IU/mL) and Genotype (1a vs 1b).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Sustained Virologic Response (SVR) Rate

Groups [1]	Cohort I - 1. Placebo + PEG + RBV vs. Cohort I - 3. Boceprevir + PEG + RBV - 44 Weeks
Method [2]	Cochran-Mantel Haenszel Chi-square test
P Value [3]	<0.0001
The difference in SVR [4]	28.3
95% Confidence Interval	20.8 to 35.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Adjustments were made for for baseline stratification factors: viral load (>400,000 vs. ≤400,000 IU/mL) and Genotype (1a vs 1b).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Sustained Virologic Response (SVR) Rate

Groups [1]	Cohort II - 1. Placebo + PEG + RBV vs. Cohort II - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)
Method [2]	Cochran-Mantel Haenszel Chi-square test
P Value [3]	0.0440
The difference in SVR [4]	19.2
95% Confidence Interval	1.6 to 36.9

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Adjustments were made for the baseline stratification factors: viral load (>400,000 vs. ≤400,000 IU/mL) and Genotype (1a vs 1b).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Sustained Virologic Response (SVR) Rate

Groups [1]	Cohort II - 1. Placebo + PEG + RBV vs. Cohort II - 3. Boceprevir + PEG + RBV - 44 Weeks
Method [2]	Cochran-Mantel Haenszel Chi-square
P Value [3]	0.0035
The difference in SVR [4]	29.7
95% Confidence Interval	12.2 to 47.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Adjustments were made for the baseline stratification factors: viral load (>400,000 vs. ≤400,000 IU/mL) and Genotype (1a vs 1b).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Sustained Virologic Response (SVR) Rate in Participants Treated With Study Drug (Boceprevir or Placebo) [Time Frame: At FW 24]

Measure Type	Secondary
Measure Title	Sustained Virologic Response (SVR) Rate in Participants Treated With Study Drug (Boceprevir or Placebo)
Measure Description	Previously untreated adults with CHC genotype 1 were treated with the assigned study medication. Participants who had undetectable plasma HCV-RNA at FW 24 had achieved SVR. SVR rate was the percentage of participants treated with at least one dose of boceprevir or placebo who had achieved SVR. HCV-RNA in participant's plasma samples was detected by a nucleic acid amplification assay with a limit of detection of 9.3 IU/mL. If a participant was missing data at FW 24 after having had undetectable HCV-RNA at FW 12, the participant was to be considered to have a SVR.
Time Frame	At FW 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Modified intent-to-treat set (mITT). All randomized participants who received at least one dose of boceprevir or placebo.

Reporting Groups

	Description
Cohort I - 1. Placebo + PEG + RBV	Cohort I (White participants) treated with PegIntron (PEG) 1.5 µg/kg + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by placebo + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Cohort I - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort I (White participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 24 weeks. Participants were offered a response guided therapy (RGT) at treatment week 28. • At the Treatment Week 28 visit, participants whose HCV-RNA was undetectable at Treatment Week 8 and at all subsequent assays (up to Treatment Week 24), will proceed to the 44-week follow-up. • At the Treatment Week 28 visit, participants with detectable HCV-RNA at Treatment Week 8 or at any subsequent assays will continue on therapy with placebo + PEG 1.5 µg/kg + RBV (WBD) for an additional 20 weeks, to complete a total of 48 weeks on treatment with 24 weeks post-treatment follow-up.
Cohort I - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort I (White participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Cohort II - 1. Placebo + PEG + RBV	Cohort II (Black participants) treated with PegIntron (PEG) 1.5 µg/kg + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by placebo + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Cohort II - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort II (Black participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 24 weeks. Participants were offered a response guided therapy (RGT) at treatment week 28. • At the Treatment Week 28 visit, participants whose HCV-RNA was undetectable at Treatment Week 8 and at all subsequent assays (up to Treatment Week 24), will proceed to the 44-week follow-up. • At the Treatment Week 28 visit, participants with detectable HCV-RNA at Treatment Week 8 or at any subsequent assays will continue on therapy with placebo + PEG 1.5 µg/kg + RBV (WBD) for an additional 20 weeks, to complete

	a total of 48 weeks on treatment with 24 weeks post-treatment follow-up.
Cohort II - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort II (Black participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.

Measured Values

	Cohort I - 1. Placebo + PEG + RBV	Cohort I - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort I - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort II - 1. Placebo + PEG + RBV	Cohort II - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort II - 3. Boceprevir + PEG + RBV - 44 Weeks
Number of Participants Analyzed [units: participants]	**297**	**303**	**299**	**47**	**47**	**55**
Sustained Virologic Response (SVR) Rate in Participants Treated With Study Drug (Boceprevir or Placebo) [units: Percentage of participants]	**42.1**	**69.6**	**71.2**	**25.5**	**46.8**	**52.7**

Statistical Analysis 1 for Sustained Virologic Response (SVR) Rate in Participants Treated With Study Drug (Boceprevir or Placebo)

Groups [1]	Cohort I - 1. Placebo + PEG + RBV vs. Cohort I - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)
Method [2]	Cochran-Mantel Haenszel Chi-square
P Value [3]	<0.0001
The difference in SVR rates [4]	27.5
95% Confidence Interval	19.2 to 35.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Adjustments were made for the baseline stratification factors: viral load (>400,000 vs. ≤400,000 IU/mL) and Genotype (1a vs 1b).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Sustained Virologic Response (SVR) Rate in Participants Treated With Study Drug (Boceprevir or Placebo)

Groups [1]	Cohort I - 1. Placebo + PEG + RBV vs. Cohort I - 3. Boceprevir + PEG + RBV - 44 Weeks
Method [2]	Cochran-Mantel Haenszel Chi-square
P Value [3]	<0.0001
The difference in SVR rates [4]	29.1
95% Confidence Interval	21.5 to 36.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Adjustments were made for the baseline stratification factors: viral load (>400,000 vs. ≤400,000 IU/mL) and Genotype (1a vs 1b).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Sustained Virologic Response (SVR) Rate in Participants Treated With Study Drug (Boceprevir or Placebo)

Groups [1]	Cohort II - 1. Placebo + PEG + RBV vs. Cohort II - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)
Method [2]	Cochran-Mantel Haenszel Chi-square test
P Value [3]	0.0366
The difference in SVR [4]	21.3
95% Confidence Interval	2.3 to 40.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Adjustments were made for the baseline stratification factors: viral load (>400,000 vs. ≤400,000 IU/mL) and Genotype (1a vs 1b).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Sustained Virologic Response (SVR) Rate in Participants Treated With Study Drug (Boceprevir or Placebo)

Groups [1]	Cohort II - 1. Placebo + PEG + RBV vs. Cohort II - 3. Boceprevir + PEG + RBV - 44 Weeks
Method [2]	Cochran-Mantel Haenszel Chi-square
P Value [3]	0.0107
The difference in SVR [4]	27.2
95% Confidence Interval	9.0 to 45.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Adjustments were made for the baseline stratification factors: viral load (>400,000 vs. ≤400,000 IU/mL) and Genotype (1a vs 1b).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical

	significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

3. Secondary: Number of Participants With Undetectable HCV-RNA at Follow-up Week 12 and at 72 Weeks After Randomization. [Time Frame: At FW 12 and at 72 weeks after randomization]

Measure Type	Secondary
Measure Title	Number of Participants With Undetectable HCV-RNA at Follow-up Week 12 and at 72 Weeks After Randomization.
Measure Description	Previously untreated adults with CHC genotype 1 were treated with the assigned study medication. The number of participants who had undetectable plasma HCV-RNA at FW 12, and 72 weeks after randomization are reported. HCV-RNA was detected by a nucleic acid amplification test and the limit of detection for this assay is 9.3 IU/mL.
Time Frame	At FW 12 and at 72 weeks after randomization
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS). All randomized participants who received at least one dose of any study medication (PEG, RBV or boceprevir).

Reporting Groups

	Description
Cohort I - 1. Placebo + PEG + RBV	Cohort I (White participants) treated with PegIntron (PEG) 1.5 µg/kg + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by placebo + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Cohort I - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort I (White participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 24 weeks. Participants were offered a response guided therapy (RGT) at treatment week 28. • At the Treatment Week 28 visit, participants whose HCV-RNA was undetectable at Treatment Week 8 and at all subsequent assays (up to Treatment Week 24), will proceed to the 44-week follow-up. • At the Treatment Week 28 visit, participants with detectable HCV-RNA at Treatment Week 8 or at any subsequent assays will continue on therapy with placebo + PEG 1.5 µg/kg + RBV (WBD) for an additional 20 weeks, to complete a total of 48 weeks on treatment with 24 weeks post-treatment follow-up.
Cohort I - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort I (White participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Cohort II - 1. Placebo + PEG + RBV	Cohort II (Black participants) treated with PegIntron (PEG) 1.5 µg/kg + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by placebo + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Cohort II - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort II (Black participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 24 weeks. Participants were offered a response guided therapy (RGT) at treatment week 28. • At the Treatment Week 28 visit, participants whose HCV-RNA was undetectable

	at Treatment Week 8 and at all subsequent assays (up to Treatment Week 24), will proceed to the 44-week follow-up. • At the Treatment Week 28 visit, participants with detectable HCV-RNA at Treatment Week 8 or at any subsequent assays will continue on therapy with placebo + PEG 1.5 µg/kg + RBV (WBD) for an additional 20 weeks, to complete a total of 48 weeks on treatment with 24 weeks post-treatment follow-up.
Cohort II - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort II (Black participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.

Measured Values

	Cohort I - 1. Placebo + PEG + RBV	Cohort I - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort I - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort II - 1. Placebo + PEG + RBV	Cohort II - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort II - 3. Boceprevir + PEG + RBV - 44 Weeks
Number of Participants Analyzed [units: participants]	**311**	**316**	**311**	**52**	**52**	**55**
Number of Participants With Undetectable HCV-RNA at Follow-up Week 12 and at 72 Weeks After Randomization. [units: Participants]						
At follow-up week 12	**127**	**209**	**209**	**11**	**21**	**29**
72 weeks after randomization	**120**	**194**	**205**	**11**	**20**	**27**

No statistical analysis provided for Number of Participants With Undetectable HCV-RNA at Follow-up Week 12 and at 72 Weeks After Randomization.

4. Secondary: Number of Participants With Early Virologic Response (Undetectable HCV-RNA at Treatment Week 2, 4, 8, 12, 16, or 20) [Time Frame: At Treatment Week 2, 4, 8, 12, 16, or 20]

Measure Type	Secondary
Measure Title	Number of Participants With Early Virologic Response (Undetectable HCV-RNA at Treatment Week 2, 4, 8, 12, 16, or 20)
Measure Description	Early virologic response was defined as undetectable HCV-RNA at in participants by treatment week 2, 4, 8, 12, 16, or 20. HCV-RNA in participant's plasma samples was detected by a nucleic acid amplification assay with a limit of detection of 9.3 IU/mL.
Time Frame	At Treatment Week 2, 4, 8, 12, 16, or 20
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS). All randomized participants who received at least one dose of any study medication (PEG, RBV or boceprevir).

Reporting Groups

	Description
Cohort I - 1. Placebo + PEG + RBV	Cohort I (White participants) treated with PegIntron (PEG) 1.5 µg/kg + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by placebo + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Cohort I - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort I (White participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 24 weeks. Participants were offered a response guided therapy (RGT) at treatment week 28. • At the Treatment Week 28 visit, participants whose HCV-RNA was undetectable at Treatment Week 8 and at all subsequent assays (up to Treatment Week 24), will proceed to the 44-week follow-up. • At the Treatment Week 28 visit, participants with detectable HCV-RNA at Treatment Week 8 or at any subsequent assays will continue on therapy with placebo + PEG 1.5 µg/kg + RBV (WBD) for an additional 20 weeks, to complete a total of 48 weeks on treatment with 24 weeks post-treatment follow-up.
Cohort I - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort I (White participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Cohort II - 1. Placebo + PEG + RBV	Cohort II (Black participants) treated with PegIntron (PEG) 1.5 µg/kg + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by placebo + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Cohort II - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort II (Black participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 24 weeks. Participants were offered a response guided therapy (RGT) at treatment week 28. • At the Treatment Week 28 visit, participants whose HCV-RNA was undetectable at Treatment Week 8 and at all subsequent assays (up to Treatment Week 24), will proceed to the 44-week follow-up. • At the Treatment Week 28 visit, participants with detectable HCV-RNA at Treatment Week 8 or at any subsequent assays will continue on therapy with placebo + PEG 1.5 µg/kg + RBV (WBD) for an additional 20 weeks, to complete a total of 48 weeks on treatment with 24 weeks post-treatment follow-up.
Cohort II - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort II (Black participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.

Measured Values

	Cohort I - 1. Placebo + PEG + RBV	Cohort I - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort I - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort II - 1. Placebo + PEG + RBV	Cohort II - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort II - 3. Boceprevir + PEG + RBV - 44 Weeks
Number of Participants Analyzed [units: participants]	**311**	**316**	**311**	**52**	**52**	**55**
Number of Participants With Early Virologic Response (Undetectable HCV-RNA at Treatment Week 2, 4, 8, 12, 16, or 20) [units: Participants]						
Treatment week 2	**8**	**11**	**8**	**0**	**1**	**0**
Treatment week 4	**28**	**18**	**20**	**2**	**1**	**0**
Treatment week 8	**56**	**190**	**182**	**4**	**18**	**22**
Treatment week 12	**108**	**237**	**231**	**10**	**25**	**33**

Treatment week 16	**138**	**231**	**237**	**15**	**26**	**36**
Treatment week 20	**157**	**231**	**231**	**15**	**27**	**32**

No statistical analysis provided for Number of Participants With Early Virologic Response (Undetectable HCV-RNA at Treatment Week 2, 4, 8, 12, 16, or 20)

5. Secondary: Number of Participants With Early Virologic Response (Undetectable HCV-RNA at Treatment Week 4, 8, 12, 16, or 20) Who Achieved SVR [Time Frame: At Treatment Week 4, 8, 12, 16, 20]

Measure Type	Secondary
Measure Title	Number of Participants With Early Virologic Response (Undetectable HCV-RNA at Treatment Week 4, 8, 12, 16, or 20) Who Achieved SVR
Measure Description	Participants with early virologic response were those who had undetectable HCV-RNA by treatment week 4, 8, 12, 16, or 20. Participants who had undetectable plasma HCV-RNA at FW 24 had SVR. The number of participants with early virologic response that also achieved SVR is reported. HCV-RNA in participant's plasma samples was detected by a nucleic acid amplification assay with a limit of detection of 9.3 IU/mL.
Time Frame	At Treatment Week 4, 8, 12, 16, 20
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants that had undetectable HCV RNA for the treatment weeks 4, 8, 12, 16, and 20.

Reporting Groups

	Description
Cohort I - 1. Placebo + PEG + RBV	Cohort I (White participants) treated with PegIntron (PEG) 1.5 µg/kg + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by placebo + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Cohort I - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort I (White participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 24 weeks. Participants were offered a response guided therapy (RGT) at treatment week 28. • At the Treatment Week 28 visit, participants whose HCV-RNA was undetectable at Treatment Week 8 and at all subsequent assays (up to Treatment Week 24), will proceed to the 44-week follow-up. • At the Treatment Week 28 visit, participants with detectable HCV-RNA at Treatment Week 8 or at any subsequent assays will continue on therapy with placebo + PEG 1.5 µg/kg + RBV (WBD) for an additional 20 weeks, to complete a total of 48 weeks on treatment with 24 weeks post-treatment follow-up.
Cohort I - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort I (White participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Cohort II - 1. Placebo + PEG + RBV	Cohort II (Black participants) treated with PegIntron (PEG) 1.5 µg/kg + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by placebo + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Cohort II - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort II (Black participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 24 weeks. Participants

	were offered a response guided therapy (RGT) at treatment week 28. • At the Treatment Week 28 visit, participants whose HCV-RNA was undetectable at Treatment Week 8 and at all subsequent assays (up to Treatment Week 24), will proceed to the 44-week follow-up. • At the Treatment Week 28 visit, participants with detectable HCV-RNA at Treatment Week 8 or at any subsequent assays will continue on therapy with placebo + PEG 1.5 µg/kg + RBV (WBD) for an additional 20 weeks, to complete a total of 48 weeks on treatment with 24 weeks post-treatment follow-up.
Cohort II - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort II (Black participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.

Measured Values

	Cohort I - 1. Placebo + PEG + RBV	Cohort I - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort I - 3. Boceprevir + PEG + RBV - 44 Weeks	Cohort II - 1. Placebo + PEG + RBV	Cohort II - 2. Boceprevir + PEG + RBV - 24 Weeks (RGT)	Cohort II - 3. Boceprevir + PEG + RBV - 44 Weeks
Number of Participants Analyzed [units: participants]	**311**	**316**	**311**	**52**	**52**	**55**
Number of Participants With Early Virologic Response (Undetectable HCV-RNA at Treatment Week 4, 8, 12, 16, or 20) Who Achieved SVR [units: Participants]						
Treatment week 4 (n=28, 18, 20, 2, 1, 0)	**27**	**16**	**18**	**2**	**1**	**0**
Treatment week 8 (n=56, 190, 182, 4, 18, 22)	**48**	**170**	**166**	**3**	**14**	**18**
Treatment week 12 (n=108, 237, 231, 10, 25, 33)	**90**	**205**	**204**	**7**	**19**	**26**
Treatment week 16 (n=138, 231, 237, 15, 26, 36)	**106**	**205**	**210**	**12**	**20**	**26**
Treatment week 20 (n=157, 231, 231, 15, 27, 32)	**118**	**201**	**208**	**12**	**21**	**26**

No statistical analysis provided for Number of Participants With Early Virologic Response (Undetectable HCV-RNA at Treatment Week 4, 8, 12, 16, or 20) Who Achieved SVR

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description

PEG + RBV	Cohort I (White participants) and Cohort II (Black participants) treated with PegIntron (PEG) 1.5 µg/kg + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by placebo + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
BOCEPREVIR + PEG + RBV - 24 WEEKS	Cohort I (White participants) and Cohort II (Black participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 24 weeks. Participants were offered a response guided therapy (RGT) at treatment week 28. • At the Treatment Week 28 visit, participants whose HCV-RNA was undetectable at Treatment Week 8 and at all subsequent assays (up to Treatment Week 24), will proceed to the 44-week follow-up. • At the Treatment Week 28 visit, participants with detectable HCV-RNA at Treatment Week 8 or at any subsequent assays will continue on therapy with placebo + PEG 1.5 µg/kg + RBV (WBD) for an additional 20 weeks, to complete a total of 48 weeks on treatment with 24 weeks post-treatment follow-up.
BOCEPRIVIR + PEG + RBV - 44 WEEKS	Cohort I (White participants) and Cohort II (Black participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.

Serious Adverse Events

	PEG + RBV	BOCEPREVIR + PEG + RBV - 24 WEEKS	BOCEPRIVIR + PEG + RBV - 44 WEEKS
Total, serious adverse events			
# participants affected / at risk	**31/363 (8.54%)**	**42/368 (11.41%)**	**45/366 (12.30%)**
Blood and lymphatic system disorders			
ANAEMIA † 1			
# participants affected / at risk	**1/363 (0.28%)**	**3/368 (0.82%)**	**4/366 (1.09%)**
# events	**1**	**5**	**7**
APLASIA PURE RED CELL † 1			
# participants affected / at risk	**0/363 (0.00%)**	**0/368 (0.00%)**	**1/366 (0.27%)**
# events	**0**	**0**	**1**
LEUKOCYTOSIS † 1			
# participants affected / at risk	**1/363 (0.28%)**	**0/368 (0.00%)**	**0/366 (0.00%)**
# events	**1**	**0**	**0**
LEUKOPENIA † 1			
# participants affected / at risk	**0/363 (0.00%)**	**0/368 (0.00%)**	**2/366 (0.55%)**
# events	**0**	**0**	**2**
NEUTROPENIA † 1			
# participants affected / at risk	**0/363 (0.00%)**	**1/368 (0.27%)**	**2/366 (0.55%)**
# events	**0**	**1**	**3**
PANCYTOPENIA † 1			
# participants affected / at risk	**0/363 (0.00%)**	**0/368 (0.00%)**	**1/366 (0.27%)**
# events	**0**	**0**	**1**
THROMBOCYTOPENIA † 1			

# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	3/366 (0.82%)
# events	0	0	3
Cardiac disorders			
ACUTE MYOCARDIAL INFARCTION † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
ATRIAL FIBRILLATION † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
ATRIAL FLUTTER † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
CARDIAC ARREST † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	1/366 (0.27%)
# events	1	0	1
CARDIO-RESPIRATORY ARREST † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
CORONARY ARTERY DISEASE † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
CORONARY ARTERY OCCLUSION † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
HYPERTROPHIC CARDIOMYOPATHY † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
MYOCARDIAL INFARCTION † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
TACHYCARDIA † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
Ear and labyrinth disorders			
DEAFNESS † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1

Endocrine disorders			
HYPOTHYROIDISM † 1			
# participants affected / at risk	**1/363 (0.28%)**	**0/368 (0.00%)**	**0/366 (0.00%)**
# events	**1**	**0**	**0**
Eye disorders			
CONJUNCTIVITIS † 1			
# participants affected / at risk	**0/363 (0.00%)**	**0/368 (0.00%)**	**1/366 (0.27%)**
# events	**0**	**0**	**1**
OPTIC NEUROPATHY † 1			
# participants affected / at risk	**0/363 (0.00%)**	**0/368 (0.00%)**	**1/366 (0.27%)**
# events	**0**	**0**	**1**
PAPILLOEDEMA † 1			
# participants affected / at risk	**0/363 (0.00%)**	**1/368 (0.27%)**	**0/366 (0.00%)**
# events	**0**	**1**	**0**
Gastrointestinal disorders			
ABDOMINAL PAIN † 1			
# participants affected / at risk	**1/363 (0.28%)**	**1/368 (0.27%)**	**1/366 (0.27%)**
# events	**1**	**1**	**1**
ABDOMINAL PAIN LOWER † 1			
# participants affected / at risk	**0/363 (0.00%)**	**0/368 (0.00%)**	**1/366 (0.27%)**
# events	**0**	**0**	**1**
COLITIS † 1			
# participants affected / at risk	**1/363 (0.28%)**	**0/368 (0.00%)**	**0/366 (0.00%)**
# events	**1**	**0**	**0**
COLONIC POLYP † 1			
# participants affected / at risk	**0/363 (0.00%)**	**0/368 (0.00%)**	**1/366 (0.27%)**
# events	**0**	**0**	**1**
GASTRITIS † 1			
# participants affected / at risk	**0/363 (0.00%)**	**0/368 (0.00%)**	**1/366 (0.27%)**
# events	**0**	**0**	**1**
GASTROINTESTINAL HAEMORRHAGE † 1			
# participants affected / at risk	**0/363 (0.00%)**	**1/368 (0.27%)**	**0/366 (0.00%)**
# events	**0**	**1**	**0**
GASTROOESOPHAGEAL REFLUX DISEASE † 1			
# participants affected / at risk	**0/363 (0.00%)**	**1/368 (0.27%)**	**0/366 (0.00%)**
# events	**0**	**1**	**0**
HAEMATEMESIS † 1			

# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
HAEMORRHOIDAL HAEMORRHAGE † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
HAEMORRHOIDS † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
MALLORY-WEISS SYNDROME † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
NAUSEA † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	1/366 (0.27%)
# events	1	0	1
PANCREATITIS † 1			
# participants affected / at risk	2/363 (0.55%)	0/368 (0.00%)	0/366 (0.00%)
# events	2	0	0
PANCREATITIS ACUTE † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
UMBILICAL HERNIA † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
VOMITING † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	2/366 (0.55%)
# events	1	0	2
General disorders			
CHEST DISCOMFORT † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	2/366 (0.55%)
# events	0	0	2
CHEST PAIN † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	4/366 (1.09%)
# events	0	1	4
DEATH † 1			
# participants affected / at risk	2/363 (0.55%)	0/368 (0.00%)	0/366 (0.00%)
# events	2	0	0
FATIGUE † 1			

# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
GENERAL PHYSICAL HEALTH DETERIORATION † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
MALAISE † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
PYREXIA † 1			
# participants affected / at risk	2/363 (0.55%)	1/368 (0.27%)	3/366 (0.82%)
# events	2	1	3
Hepatobiliary disorders			
CHOLECYSTITIS † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	1/366 (0.27%)
# events	1	0	1
CHOLECYSTITIS ACUTE † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
CHOLELITHIASIS † 1			
# participants affected / at risk	2/363 (0.55%)	0/368 (0.00%)	0/366 (0.00%)
# events	2	0	0
CHOLELITHIASIS OBSTRUCTIVE † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
Immune system disorders			
SARCOIDOSIS † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	2
Infections and infestations			
ABSCESS † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
ABSCESS LIMB † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
APPENDICITIS † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)

# events	1	0	0
ATYPICAL MYCOBACTERIAL INFECTION † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
BACTERAEMIA † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
BRONCHITIS † 1			
# participants affected / at risk	0/363 (0.00%)	2/368 (0.54%)	0/366 (0.00%)
# events	0	2	0
CELLULITIS † 1			
# participants affected / at risk	1/363 (0.28%)	1/368 (0.27%)	2/366 (0.55%)
# events	1	1	2
DIVERTICULITIS † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
ENTEROCOLITIS INFECTIOUS † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
EPIGLOTTITIS † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
GASTROENTERITIS † 1			
# participants affected / at risk	0/363 (0.00%)	2/368 (0.54%)	2/366 (0.55%)
# events	0	2	2
INFECTED BITES † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
INJECTION SITE INFECTION † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
PERIRECTAL ABSCESS † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
PNEUMONIA † 1			
# participants affected / at risk	1/363 (0.28%)	3/368 (0.82%)	1/366 (0.27%)
# events	1	4	1

PNEUMONIA PNEUMOCOCCAL † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
SCROTAL ABSCESS † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
SINUSITIS † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
STAPHYLOCOCCAL INFECTION † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
TRACHEOBRONCHITIS † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
UPPER RESPIRATORY TRACT INFECTION † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
Injury, poisoning and procedural complications			
ACCIDENTAL OVERDOSE † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
ALCOHOL POISONING † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
OVERDOSE † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	2
POST PROCEDURAL COMPLICATION † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
ROAD TRAFFIC ACCIDENT † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
SPINAL FRACTURE † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0

TRANSFUSION REACTION † 1			
# participants affected / at risk	**0/363 (0.00%)**	**0/368 (0.00%)**	**1/366 (0.27%)**
# events	**0**	**0**	**1**
VASCULAR PSEUDOANEURYSM † 1			
# participants affected / at risk	**0/363 (0.00%)**	**1/368 (0.27%)**	**0/366 (0.00%)**
# events	**0**	**1**	**0**
WOUND DEHISCENCE † 1			
# participants affected / at risk	**0/363 (0.00%)**	**0/368 (0.00%)**	**1/366 (0.27%)**
# events	**0**	**0**	**1**
Investigations			
WHITE BLOOD CELL COUNT DECREASED † 1			
# participants affected / at risk	**1/363 (0.28%)**	**0/368 (0.00%)**	**0/366 (0.00%)**
# events	**1**	**0**	**0**
Metabolism and nutrition disorders			
DEHYDRATION † 1			
# participants affected / at risk	**0/363 (0.00%)**	**0/368 (0.00%)**	**1/366 (0.27%)**
# events	**0**	**0**	**1**
HYPOKALAEMIA † 1			
# participants affected / at risk	**0/363 (0.00%)**	**2/368 (0.54%)**	**0/366 (0.00%)**
# events	**0**	**2**	**0**
HYPONATRAEMIA † 1			
# participants affected / at risk	**0/363 (0.00%)**	**1/368 (0.27%)**	**0/366 (0.00%)**
# events	**0**	**1**	**0**
Musculoskeletal and connective tissue disorders			
BACK PAIN † 1			
# participants affected / at risk	**0/363 (0.00%)**	**0/368 (0.00%)**	**1/366 (0.27%)**
# events	**0**	**0**	**1**
FLANK PAIN † 1			
# participants affected / at risk	**0/363 (0.00%)**	**1/368 (0.27%)**	**0/366 (0.00%)**
# events	**0**	**1**	**0**
GROIN PAIN † 1			
# participants affected / at risk	**0/363 (0.00%)**	**0/368 (0.00%)**	**1/366 (0.27%)**
# events	**0**	**0**	**1**
INTERVERTEBRAL DISC PROTRUSION † 1			
# participants affected / at risk	**0/363 (0.00%)**	**1/368 (0.27%)**	**0/366 (0.00%)**
# events	**0**	**1**	**0**
MUSCULOSKELETAL CHEST PAIN † 1			

# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BLADDER CANCER † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
BREAST CANCER † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	1/366 (0.27%)
# events	1	0	1
COLON CANCER † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
HEPATIC NEOPLASM MALIGNANT † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
LUNG ADENOCARCINOMA † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
PANCREATIC CARCINOMA † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
PROSTATE CANCER † 1			
# participants affected / at risk	1/363 (0.28%)	1/368 (0.27%)	0/366 (0.00%)
# events	1	1	0
Nervous system disorders			
CAROTID ARTERY STENOSIS † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
CEREBRAL ISCHAEMIA † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
DIZZINESS † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	1/366 (0.27%)
# events	1	0	2
HYPOAESTHESIA † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)

# events	1	0	0
LOSS OF CONSCIOUSNESS † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
MOTOR NEURONE DISEASE † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
MUSCLE SPASTICITY † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
SYNCOPE † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	4/366 (1.09%)
# events	0	1	4
Psychiatric disorders			
AFFECTIVE DISORDER † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	1/366 (0.27%)
# events	1	0	1
ALCOHOL ABUSE † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
ANXIETY † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
BIPOLAR I DISORDER † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
COMPLETED SUICIDE † 1			
# participants affected / at risk	1/363 (0.28%)	1/368 (0.27%)	0/366 (0.00%)
# events	1	1	0
DEPRESSION † 1			
# participants affected / at risk	1/363 (0.28%)	1/368 (0.27%)	1/366 (0.27%)
# events	1	1	1
DRUG ABUSE † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
DRUG DEPENDENCE † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)

# events	1	0	0
INTENTIONAL SELF-INJURY † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
PERSONALITY DISORDER † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
PSYCHIATRIC DECOMPENSATION † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
SUICIDAL IDEATION † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	4/366 (1.09%)
# events	1	0	4
SUICIDE ATTEMPT † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	1/366 (0.27%)
# events	1	0	1
Renal and urinary disorders			
GLOMERULONEPHRITIS MINIMAL LESION † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
RENAL TUBULAR NECROSIS † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
Reproductive system and breast disorders			
SCROTAL PAIN † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
Respiratory, thoracic and mediastinal disorders			
COUGH † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	2/366 (0.55%)
# events	0	0	2
DYSPNOEA † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
HAEMOPTYSIS † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0

PLEURAL FIBROSIS † 1			
# participants affected / at risk	0/363 (0.00%)	1/368 (0.27%)	0/366 (0.00%)
# events	0	1	0
PNEUMOTHORAX † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
PULMONARY EMBOLISM † 1			
# participants affected / at risk	0/363 (0.00%)	2/368 (0.54%)	0/366 (0.00%)
# events	0	2	0
Skin and subcutaneous tissue disorders			
PRURITUS † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
RASH ERYTHEMATOUS † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
Social circumstances			
ALCOHOL USE † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
PHYSICAL ASSAULT † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
Surgical and medical procedures			
CHOLECYSTECTOMY † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
LARYNGEAL OPERATION † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1
SKIN NEOPLASM EXCISION † 1			
# participants affected / at risk	1/363 (0.28%)	0/368 (0.00%)	0/366 (0.00%)
# events	1	0	0
Vascular disorders			
ACCELERATED HYPERTENSION † 1			
# participants affected / at risk	0/363 (0.00%)	0/368 (0.00%)	1/366 (0.27%)
# events	0	0	1

ARTERIAL THROMBOSIS LIMB † 1			
# participants affected / at risk	**0/363 (0.00%)**	**0/368 (0.00%)**	**1/366 (0.27%)**
# events	**0**	**0**	**1**
HYPERTENSIVE CRISIS † 1			
# participants affected / at risk	**0/363 (0.00%)**	**0/368 (0.00%)**	**1/366 (0.27%)**
# events	**0**	**0**	**1**
HYPOTENSION † 1			
# participants affected / at risk	**0/363 (0.00%)**	**1/368 (0.27%)**	**1/366 (0.27%)**
# events	**0**	**1**	**1**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
PEG + RBV	Cohort I (White participants) and Cohort II (Black participants) treated with PegIntron (PEG) 1.5 µg/kg + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by placebo + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
BOCEPREVIR + PEG + RBV - 24 WEEKS	Cohort I (White participants) and Cohort II (Black participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 24 weeks. Participants were offered a response guided therapy (RGT) at treatment week 28. • At the Treatment Week 28 visit, participants whose HCV-RNA was undetectable at Treatment Week 8 and at all subsequent assays (up to Treatment Week 24), will proceed to the 44-week follow-up. • At the Treatment Week 28 visit, participants with detectable HCV-RNA at Treatment Week 8 or at any subsequent assays will continue on therapy with placebo + PEG 1.5 µg/kg + RBV (WBD) for an additional 20 weeks, to complete a total of 48 weeks on treatment with 24 weeks post-treatment follow-up.
BOCEPRIVIR + PEG + RBV - 44 WEEKS	Cohort I (White participants) and Cohort II (Black participants) treated with PEG 1.5 µg/kg + RBV (WBD) for 4 weeks followed by boceprevir + PEG 1.5 µg/kg + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.

Other Adverse Events

	PEG + RBV	**BOCEPREVIR + PEG + RBV - 24 WEEKS**	**BOCEPRIVIR + PEG + RBV - 44 WEEKS**

Total, other (not including serious) adverse events			
# participants affected / at risk	**353/363 (97.25%)**	**365/368 (99.18%)**	**363/366 (99.18%)**
Blood and lymphatic system disorders			
ANAEMIA † 1			
# participants affected / at risk	**107/363 (29.48%)**	**182/368 (49.46%)**	**179/366 (48.91%)**
# events	**188**	**292**	**352**
LEUKOPENIA † 1			
# participants affected / at risk	**33/363 (9.09%)**	**31/368 (8.42%)**	**45/366 (12.30%)**
# events	**81**	**83**	**126**
NEUTROPENIA † 1			
# participants affected / at risk	**77/363 (21.21%)**	**91/368 (24.73%)**	**93/366 (25.41%)**
# events	**208**	**216**	**257**
THROMBOCYTOPENIA † 1			
# participants affected / at risk	**7/363 (1.93%)**	**16/368 (4.35%)**	**19/366 (5.19%)**
# events	**16**	**50**	**38**
Eye disorders			
DRY EYE † 1			
# participants affected / at risk	**16/363 (4.41%)**	**13/368 (3.53%)**	**22/366 (6.01%)**
# events	**16**	**13**	**24**
VISION BLURRED † 1			
# participants affected / at risk	**14/363 (3.86%)**	**23/368 (6.25%)**	**22/366 (6.01%)**
# events	**15**	**25**	**25**
Gastrointestinal disorders			
ABDOMINAL PAIN † 1			
# participants affected / at risk	**20/363 (5.51%)**	**25/368 (6.79%)**	**23/366 (6.28%)**
# events	**30**	**28**	**28**
ABDOMINAL PAIN UPPER † 1			
# participants affected / at risk	**32/363 (8.82%)**	**30/368 (8.15%)**	**44/366 (12.02%)**
# events	**40**	**41**	**54**
CONSTIPATION † 1			
# participants affected / at risk	**32/363 (8.82%)**	**22/368 (5.98%)**	**32/366 (8.74%)**
# events	**34**	**24**	**34**
DIARRHOEA † 1			
# participants affected / at risk	**79/363 (21.76%)**	**80/368 (21.74%)**	**100/366 (27.32%)**
# events	**103**	**104**	**125**
DRY MOUTH † 1			
# participants affected / at risk	**40/363 (11.02%)**	**39/368 (10.60%)**	**43/366 (11.75%)**
# events	**45**	**42**	**51**
DYSPEPSIA † 1			

# participants affected / at risk	32/363 (8.82%)	29/368 (7.88%)	33/366 (9.02%)
# events	39	35	40
GASTROOESOPHAGEAL REFLUX DISEASE † 1			
# participants affected / at risk	8/363 (2.20%)	19/368 (5.16%)	20/366 (5.46%)
# events	9	22	22
NAUSEA † 1			
# participants affected / at risk	153/363 (42.15%)	175/368 (47.55%)	159/366 (43.44%)
# events	199	231	212
VOMITING † 1			
# participants affected / at risk	57/363 (15.70%)	75/368 (20.38%)	70/366 (19.13%)
# events	70	99	90
General disorders			
ASTHENIA † 1			
# participants affected / at risk	70/363 (19.28%)	55/368 (14.95%)	70/366 (19.13%)
# events	129	86	132
CHILLS † 1			
# participants affected / at risk	102/363 (28.10%)	134/368 (36.41%)	121/366 (33.06%)
# events	114	156	139
FATIGUE † 1			
# participants affected / at risk	217/363 (59.78%)	196/368 (53.26%)	209/366 (57.10%)
# events	279	250	290
INFLUENZA LIKE ILLNESS † 1			
# participants affected / at risk	93/363 (25.62%)	91/368 (24.73%)	83/366 (22.68%)
# events	160	113	102
INJECTION SITE ERYTHEMA † 1			
# participants affected / at risk	47/363 (12.95%)	46/368 (12.50%)	37/366 (10.11%)
# events	55	48	38
INJECTION SITE REACTION † 1			
# participants affected / at risk	44/363 (12.12%)	45/368 (12.23%)	39/366 (10.66%)
# events	46	46	39
IRRITABILITY † 1			
# participants affected / at risk	86/363 (23.69%)	81/368 (22.01%)	83/366 (22.68%)
# events	106	104	111
PAIN † 1			
# participants affected / at risk	34/363 (9.37%)	41/368 (11.14%)	37/366 (10.11%)
# events	36	43	41

PYREXIA † 1			
# participants affected / at risk	120/363 (33.06%)	123/368 (33.42%)	117/366 (31.97%)
# events	196	180	218
Infections and infestations			
SINUSITIS † 1			
# participants affected / at risk	15/363 (4.13%)	16/368 (4.35%)	19/366 (5.19%)
# events	18	20	22
Investigations			
WEIGHT DECREASED † 1			
# participants affected / at risk	46/363 (12.67%)	43/368 (11.68%)	52/366 (14.21%)
# events	54	50	64
Metabolism and nutrition disorders			
DECREASED APPETITE † 1			
# participants affected / at risk	90/363 (24.79%)	97/368 (26.36%)	89/366 (24.32%)
# events	101	107	98
Musculoskeletal and connective tissue disorders			
ARTHRALGIA † 1			
# participants affected / at risk	66/363 (18.18%)	69/368 (18.75%)	72/366 (19.67%)
# events	84	87	103
BACK PAIN † 1			
# participants affected / at risk	40/363 (11.02%)	30/368 (8.15%)	40/366 (10.93%)
# events	45	33	45
MUSCLE SPASMS † 1			
# participants affected / at risk	23/363 (6.34%)	15/368 (4.08%)	18/366 (4.92%)
# events	25	20	20
MYALGIA † 1			
# participants affected / at risk	94/363 (25.90%)	78/368 (21.20%)	92/366 (25.14%)
# events	125	98	120
PAIN IN EXTREMITY † 1			
# participants affected / at risk	19/363 (5.23%)	11/368 (2.99%)	21/366 (5.74%)
# events	21	12	24
Nervous system disorders			
DISTURBANCE IN ATTENTION † 1			
# participants affected / at risk	27/363 (7.44%)	22/368 (5.98%)	18/366 (4.92%)
# events	30	23	18
DIZZINESS † 1			
# participants affected / at risk	59/363 (16.25%)	80/368 (21.74%)	66/366 (18.03%)
# events	74	97	70

DYSGEUSIA † 1			
# participants affected / at risk	64/363 (17.63%)	137/368 (37.23%)	156/366 (42.62%)
# events	68	143	164
HEADACHE † 1			
# participants affected / at risk	153/363 (42.15%)	168/368 (45.65%)	167/366 (45.63%)
# events	264	233	311
MEMORY IMPAIRMENT † 1			
# participants affected / at risk	21/363 (5.79%)	9/368 (2.45%)	24/366 (6.56%)
# events	21	9	28
PARAESTHESIA † 1			
# participants affected / at risk	13/363 (3.58%)	10/368 (2.72%)	19/366 (5.19%)
# events	32	11	23
Psychiatric disorders			
ANXIETY † 1			
# participants affected / at risk	42/363 (11.57%)	50/368 (13.59%)	48/366 (13.11%)
# events	49	57	65
DEPRESSION † 1			
# participants affected / at risk	78/363 (21.49%)	82/368 (22.28%)	69/366 (18.85%)
# events	86	103	85
INSOMNIA † 1			
# participants affected / at risk	118/363 (32.51%)	117/368 (31.79%)	122/366 (33.33%)
# events	137	145	141
MOOD SWINGS † 1			
# participants affected / at risk	6/363 (1.65%)	13/368 (3.53%)	19/366 (5.19%)
# events	7	17	21
Respiratory, thoracic and mediastinal disorders			
COUGH † 1			
# participants affected / at risk	76/363 (20.94%)	56/368 (15.22%)	74/366 (20.22%)
# events	87	69	100
DYSPNOEA † 1			
# participants affected / at risk	59/363 (16.25%)	68/368 (18.48%)	84/366 (22.95%)
# events	66	87	94
DYSPNOEA EXERTIONAL † 1			
# participants affected / at risk	30/363 (8.26%)	42/368 (11.41%)	31/366 (8.47%)
# events	33	44	39
EPISTAXIS † 1			
# participants affected / at risk	13/363 (3.58%)	19/368 (5.16%)	21/366 (5.74%)
# events	15	23	21

OROPHARYNGEAL PAIN † 1			
# participants affected / at risk	**22/363 (6.06%)**	**14/368 (3.80%)**	**33/366 (9.02%)**
# events	**24**	**18**	**34**
Skin and subcutaneous tissue disorders			
ALOPECIA † 1			
# participants affected / at risk	**99/363 (27.27%)**	**75/368 (20.38%)**	**104/366 (28.42%)**
# events	**105**	**82**	**109**
DRY SKIN † 1			
# participants affected / at risk	**66/363 (18.18%)**	**67/368 (18.21%)**	**86/366 (23.50%)**
# events	**77**	**72**	**98**
PRURITUS † 1			
# participants affected / at risk	**98/363 (27.00%)**	**87/368 (23.64%)**	**94/366 (25.68%)**
# events	**130**	**101**	**138**
RASH † 1			
# participants affected / at risk	**83/363 (22.87%)**	**93/368 (25.27%)**	**88/366 (24.04%)**
# events	**124**	**111**	**119**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

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More Information

Hide More Information

Certain Agreements:

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

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

The agreement is:

☐ 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 **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ 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**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description:
In this multicenter trial, initially, the investigator may only publish study results together with the other sites, unless specific written

permission is obtained in advance from the sponsor.

The 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 45 day period from the time submitted to the sponsor for review.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp.
e-mail: ClinicalTrialsDisclosure@merck.com

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Ferrante SA, Chhatwal J, Brass CA, El Khoury AC, Poordad F, Bronowicki JP, Elbasha EH. Boceprevir for previously untreated patients with chronic hepatitis C Genotype 1 infection: a US-based cost-effectiveness modeling study. BMC Infect Dis. 2013 Apr 27;13:190. doi: 10.1186/1471-2334-13-190.

Poordad F, Bronowicki JP, Gordon SC, Zeuzem S, Jacobson IM, Sulkowski MS, Poynard T, Morgan TR, Molony C, Pedicone LD, Sings HL, Burroughs MH, Sniukiene V, Boparai N, Goteti VS, Brass CA, Albrecht JK, Bacon BR; SPRINT-2 and RESPOND-2 Investigators. Factors that predict response of patients with hepatitis C virus infection to boceprevir. Gastroenterology. 2012 Sep;143(3):608-18.e1-5. doi: 10.1053/j.gastro.2012.05.011. Epub 2012 May 21.

Poordad F, McCone J Jr, Bacon BR, Bruno S, Manns MP, Sulkowski MS, Jacobson IM, Reddy KR, Goodman ZD, Boparai N, DiNubile MJ, Sniukiene V, Brass CA, Albrecht JK, Bronowicki JP; SPRINT-2 Investigators. Boceprevir for untreated chronic HCV genotype 1 infection. N Engl J Med. 2011 Mar 31;364(13):1195-206. doi: 10.1056/NEJMoa1010494.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00705432 History of Changes
Obsolete Identifiers:	NCT00795431
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Study First Received:	June 24, 2008
Results First Received:	May 13, 2011
Last Updated:	October 16, 2015
Health Authority:	United States: Food and Drug Administration

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