Boceprevir (SCH 503034) Plus Peg-Intron, With and Without Added Ribavirin, in Patients With Chronic Hepatitis C, Genotype 1, Who Did Not Respond to Previous Treatment With Peginterferon Alfa Plus Ribavirin (Study P03659AM2)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00160251

First received: September 8, 2005
Last updated: October 13, 2015
Last verified: October 2015
History of Changes

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

Purpose

The primary objective of this study is to determine the safe and effective dose range of boceprevir (SCH 503034) in combination with PEG-Intron in adult subjects who have chronic hepatitis C without cirrhosis, and who have failed an adequate course of combination therapy with peginterferon-alfa plus ribavirin. A secondary objective is to explore whether ribavirin provides an additional benefit when combined with PEG-Intron plus boceprevir.

Condition	Intervention	Phase
Chronic Hepatitis C	Drug: Boceprevir (BOC) Biological: PegIntron (PEG) Drug: Ribavirin (RBV)	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double-Blind
Primary Purpose: Treatment

Official Title: PEG-Intron/REBETOL vs PEG-Intron/ SCH 503034 With and Without Ribavirin in Chronic Hepatitis C Virus Genotype 1 (HCV-1) Peginterferon Alfa/Ribavirin Nonresponders: A SCH 503034 Dose-Finding Phase 2 Study

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:

- Percent of Participants Who Were Hepatitis C Virus Ribonucleic Acid (HCV-RNA) Negative at the End of Treatment (EoT)
  [Time Frame: Baseline up to Week 49] [Designated as safety issue: No]

  Sustained Viral Response (SVR) was defined as the percentage of participants with HCV-RNA undetectable at the follow-up Week 24. All percentages were based on the total number of participants originally randomized/enrolled to that particular arm. For Arm 1B, the denominator for the percentages was the number who received at least 1 dose of BOC. Arm 1A was not analyzed.

- Percent of Participants Who Achieved Sustained Virologic Response (SVR) [Time Frame: Baseline up to Week 73 [24 weeks after end of treatment (EoT)]] [Designated as safety issue: No]

  SVR was defined as the percentage of participants with Hepatitis C Virus Ribonucleic Acid (HCV-RNA) undetectable at the follow-up Week 24. All percentages were based on the total number of participants originally randomized/enrolled to that particular arm. For Arm 1B, the denominator for the percentages was the number who received at least 1 dose of BOC. Arm 1A was not analyzed.

Secondary Outcome Measures:

- Percent of Participants Who Achieved Sustained Viral Response (SVR) by Time to First Negative HCV-RNA [Time Frame: Baseline up to Week 73 [24 weeks after EoT]] [Designated as safety issue: No]

  Percentage of participants who became HCV-RNA undetectable within the first 13 weeks and subsequently became HCV-RNA positive were not considered negative for this analysis.

- Percentage of Participants Who Were HCV-RNA Negative at EoT After Receiving 1 Week of Treatment With PegIntron (PEG) by Log Drop
  [Time Frame: Week 1 and Week 49] [Designated as safety issue: No]

  For each log drop category (<0, 0 to 0.5, 0.5 to <1, 1 to <1.5, ≥1.5, and Missing), the percentage of participants receiving combination therapy who were HCV-RNA negative at EoT (Week 49) was calculated as follows: Number of participants in a log category who were HCV-RNA negative divided by the total number of participants in that log drop category (n). Percentages were NOT derived using treatment arm N values. The sum of the n values for all 6 log drop categories within a treatment arm equals the overall N for that treatment group.

- Percent of Participants With Virologic Response Prior to Amendment 2 [Time Frame: Week 3, Week 5, Week 13]
  [Designated as safety issue: No]

  Virologic response was defined as the percentage of participants with Hepatitis C Virus Ribonucleic Acid (HCV-RNA) ≤10,000 IU/mL.

- Peak Plasma Concentration of Boceprevir (BOC) [Time Frame: All visits during treatment (baseline to Week 49) except Day 1 of Week 1]
  [Designated as safety issue: No]

  All plasma samples were assayed using a validated liquid chromatography with tandem mass spectrometric detection (LCMS/MS) method.

- Area Under the Plasma Concentration-time Curve of Boceprevir Plasma Concentration for an 8-hour Dosing Period [Time Frame: All visits during treatment (baseline to Week 49) except Day 1 of Week 1] [Designated as safety issue: No]

  All plasma samples were assayed using a validated liquid chromatography with tandem mass spectrometric detection (LCMS/MS) method. The dosing interval of 8 hours is represented as the hr in the unit of measure.

- Trough Plasma Concentration Level [Time Frame: All visits during treatment (baseline to Week 49) except Day 1 of Week 1]
  [Designated as safety issue: No]

  All plasma samples were assayed using a validated liquid chromatography with tandem mass spectrometric detection (LCMS/MS) method.

- Change in Alanine Aminotransferase (ALT) Levels [Time Frame: Baseline up to dosing change (> 25 weeks)]
  [Designated as safety issue: Yes]

  Change in ALT levels during initial treatment regimen and after rolling into amendment 2 as compared to baseline.

- Number of Participants Who Were HCV-RNA Negative During Amendment 2 (AM2) for Those Who Started on Arms 2 (PEG+BOC 100), 3 (PEG+BOC 200), 4 (PEG+BOC 400 [48 Weeks]), 6 (PEG+BOC 400 [24 Weeks]) [Time Frame: From dosing change to end of follow-up (Week 73)(up to 48 weeks)] [Designated as safety issue: No]

  Log drop at baseline of dosing change = difference of log viral loads between baseline (closest to the treatment begin date) and dosing change baseline (virology value closest to the dosing change begin date).

- Number of Participants Who Were HCV-RNA Negative During Amendment 2 (AM2) for Those Who Started on PegIntron (PEG) + Rebetol (RVB) + Boceprevir (BOC) 400 (Arm 5) [Time Frame: From dosing change to end of follow-up (Week 73)(up to 48 weeks)] [Designated as safety issue: No]

  Log drop at baseline of dosing change = difference of log viral loads between baseline (closest to the treatment begin date) and dosing change baseline (virology value closest to the dosing change begin date).

- Number of Participants Who Were HCV-RNA Negative During Amendment 2 (AM2) for Those Who Started on PegIntron (PEG) + Boceprevir (BOC) 800 (Arm 7) [Time Frame: From dosing change to end of follow-up (Week 73) (up to 48 weeks)] [Designated as safety issue: No]

  Log drop at baseline of dosing change = difference of log viral loads between baseline (closest to the treatment begin date) and dosing change baseline (virology value closest to the dosing change begin date).

Enrollment: 357
Study Start Date: September 2005
Study Completion Date: July 2007
Primary Completion Date: July 2007 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: Arm 1A: PegIntron (PEG) + Ribavirin (RBV) A single dose of PEG is given first, followed 1 week later by PEG + RBV for 12 weeks. If HCV-RNA is undetected, PEG + RBV will continue for another 36 weeks.	Biological: PegIntron (PEG) 1.5 mcg/kg weekly subcutaneously Drug: Ribavirin (RBV) 200 mg capsules taken twice daily (BID) (total daily dose of 800-1400 mg/day, depending on weight [weight-based dosing {WBD}])
Active Comparator: Arm 1B: PegIntron (PEG)+Ribavirin (RBV)+Boceprevir (BOC) 400 A single dose of PEG is given first, followed 1 week later by PEG + RBV for 12 weeks. If HCV-RNA is detectable, BOC 400 mg TID will be added for 36 weeks. By second protocol amendment to P03659, participants will be rolled over into Arm 8 for the remainder of the treatment period.	Drug: Boceprevir (BOC) 100 or 200 mg capsules taken orally as 100 mg, 200 mg, 400 mg, or 800 mg TID Other Name: SCH 503034 Biological: PegIntron (PEG) 1.5 mcg/kg weekly subcutaneously Drug: Ribavirin (RBV) 200 mg capsules taken twice daily (BID) (total daily dose of 800-1400 mg/day, depending on weight [weight-based dosing {WBD}])
Experimental: Arm 2: PegIntron (PEG) + Boceprevir (BOC) 100 (48 weeks) A single dose of PEG is given first, followed 1 week later by PEB + BOC 100 for 48 weeks. By second protocol amendment to P03659, participants will be rolled over into Arm 8 for the remainder of the treatment period.	Drug: Boceprevir (BOC) 100 or 200 mg capsules taken orally as 100 mg, 200 mg, 400 mg, or 800 mg TID Other Name: SCH 503034 Biological: PegIntron (PEG) 1.5 mcg/kg weekly subcutaneously
Experimental: Arm 3: PegIntron (PEG) + Boceprevir (BOC) 200 (48 Weeks) A single dose of PEG is given first, followed 1 week later by PEG + BOC 200 for 48 weeks. By second protocol amendment to P03659, participants will be rolled over into Arm 8 for the remainder of the treatment period.	Drug: Boceprevir (BOC) 100 or 200 mg capsules taken orally as 100 mg, 200 mg, 400 mg, or 800 mg TID Other Name: SCH 503034 Biological: PegIntron (PEG) 1.5 mcg/kg weekly subcutaneously
Experimental: Arm 4: PegIntron (PEG) + Boceprevir (BOC) 400 (48 weeks) A single dose of PEG is given first, followed 1 week later by PEG + BOC 400 for 48 weeks. By second protocol amendment to P03659, participants will be rolled over into Arm 8 for the remainder of the treatment period.	Drug: Boceprevir (BOC) 100 or 200 mg capsules taken orally as 100 mg, 200 mg, 400 mg, or 800 mg TID Other Name: SCH 503034 Biological: PegIntron (PEG) 1.5 mcg/kg weekly subcutaneously

Experimental: Arm 5: PegIntron (PEG)+Ribavirin (RBV)+Boceprevir (BOC) 400 A single dose of PEG is given first, followed 1 week later by PEG + RBV + BOC 400 for 48 weeks. By second protocol amendment to P03659, participants will be rolled over into Arm 8 for the remainder of the treatment period.	Drug: Boceprevir (BOC) 100 or 200 mg capsules taken orally as 100 mg, 200 mg, 400 mg, or 800 mg TID Other Name: SCH 503034 Biological: PegIntron (PEG) 1.5 mcg/kg weekly subcutaneously Drug: Ribavirin (RBV) 200 mg capsules taken twice daily (BID) (total daily dose of 800-1400 mg/day, depending on weight [weight-based dosing {WBD}])
Experimental: Arm 6: PegIntron (PEG) + Boceprevir (BOC) 400 (24 Weeks) A single dose of PEG is given first, followed 1 week later by PEG + BOC 400 for 24 weeks. By second protocol amendment to P03659, participants will be rolled over into Arm 8 for the remainder of the treatment period.	Drug: Boceprevir (BOC) 100 or 200 mg capsules taken orally as 100 mg, 200 mg, 400 mg, or 800 mg TID Other Name: SCH 503034 Biological: PegIntron (PEG) 1.5 mcg/kg weekly subcutaneously
Experimental: Arm 7: PegIntron (PEG) + Boceprevir (BOC) 800 By first protocol amendment to P03659, this non-randomized arm is added. A single dose of PEG is given first, followed 1 week later by PEG + BOC 800 for 24 weeks. By second protocol amendment to P03659, participants will be rolled over into Arm 8 for the remainder of the treatment period.	Drug: Boceprevir (BOC) 100 or 200 mg capsules taken orally as 100 mg, 200 mg, 400 mg, or 800 mg TID Other Name: SCH 503034 Biological: PegIntron (PEG) 1.5 mcg/kg weekly subcutaneously
Experimental: Arm 8: PegIntron (PEG)+Ribavirin (RBV)+Boceprevir (BOC) 800 By second protocol amendment to P03659, participants from all arms except Arm 1A will be rolled over into PEG + RBV + BOC 800 for the remainder of the treatment period.	Drug: Boceprevir (BOC) 100 or 200 mg capsules taken orally as 100 mg, 200 mg, 400 mg, or 800 mg TID Other Name: SCH 503034 Biological: PegIntron (PEG) 1.5 mcg/kg weekly subcutaneously Drug: Ribavirin (RBV) 200 mg capsules taken twice daily (BID) (total daily dose of 800-1400 mg/day, depending on weight [weight-based dosing {WBD}])

Eligibility

Ages Eligible for Study: 18 Years to 65 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Key inclusion criteria:

- Documented infection with chronic hepatitis C (CHC), genotype 1.
- Documented failure to respond to an adequate course of treatment (minimum 12 weeks) with peginterferon-alfa plus ribavirin (failure defined as <2 log drop in HCV-RNA after 12 weeks of therapy or those who never become Hepatitis C Virus Ribonucleic Acid (HCV)-RNA negative)
- No evidence of cirrhosis on liver biopsy.
- Results of physical examination and laboratory tests within specified ranges.
- Abstinence from use of abused substances.

Key exclusion criteria:

- Women who are pregnant or nursing a child.
- Patients with cirrhosis, co-infection with Hepatitis B or human immunodeficiency virus (HIV), and African-American patients (by protocol amendment 2, African-American patients can enroll).

- Previous treatment with any Hepatitis C Virus (HCV) polymerase or protease inhibitor.
- Patients who relapsed following response to previous treatment.
- Evidence of advanced liver disease, or liver disease from a cause other than CHC.
- Pre-existing psychiatric condition.

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

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00160251 History of Changes
Other Study ID Numbers:	P03659
Study First Received:	September 8, 2005
Results First Received:	May 13, 2011
Last Updated:	October 13, 2015
Health Authority:	United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
PEG-Intron
Ribavirin
Protease Inhibitor

Additional relevant MeSH terms:

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

ClinicalTrials.gov processed this record on May 08, 2016

TO TOP

For Patients and Families | For Researchers | For Study Record Managers

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK

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This study has been completed.

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First received: September 8, 2005
Last updated: October 13, 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; Primary Purpose: Treatment
Condition:	Chronic Hepatitis C
Interventions:	Drug: Boceprevir (BOC) Biological: PegIntron (PEG) Drug: Ribavirin (RBV)

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
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Arm 1A: PEG + RBV	A single dose of PEG was given first, followed 1 week A single dose of PEG was given first, followed 1 week later by PEG + RBV + BOC 400. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 1B: PEG + RBV + BOC	A single dose of PEG was given first, followed 1 week later by PEG + RBV for 12 weeks. If HCV-RNA was detectable, BOC 400 was added for another 36 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 2: PEG + BOC 100 (48 Weeks)	A single dose of PEG was given first, followed 1 week later by PEG + BOC 100 for 48 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 3: PEG + BOC 200 (48 Weeks)	A single dose of PEG was given first, followed 1 week later by PEG + BOC 200 for 48 weeks. By protocol

	amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 5: PEG + RBV + BOC 400	A single dose of PEG was given first, followed 1 week A single dose of PEG was given first, followed 1 week later by PEG + RBV + BOC 400. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
ARM 4+6: PEG + BOC 400 (24 + 48 Weeks)	A single dose of PEG was given first, followed 1 week A single dose of PEG was given first, followed 1 week later by PEG + RBV + BOC 400. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 7: PEG + BOC 800	A single dose of PEG was given first, followed 1 week later by PEG + BOC 800. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 8: PEG + RBV + BOC 800	By protocol amendment 2, participants from all arms except Arm 1A were rolled over into PEG + RBV + BOC 800 for the remainder of the treatment period.

Participant Flow for 2 periods

Period 1: Prior to Amendment 2

	Arm 1A: PEG + RBV	Arm 1B: PEG + RBV + BOC	Arm 2: PEG + BOC 100 (48 Weeks)	Arm 3: PEG + BOC 200 (48 Weeks)	Arm 5: PEG + RBV + BOC 400	ARM 4+6: PEG + BOC 400 (24 + 48 Weeks)	Arm 7: PEG + BOC 800	Arm 8: PEG + RBV + BOC 800
STARTED	15	34	48	49	49	97	65	0
COMPLETED	6	28	4	9	21	14	61	0
NOT COMPLETED	9	6	44	40	28	83	4	0
Adverse Event	2	1	3	1	1	1	1	0
Lack of Efficacy	0	4	37	35	24	55	0	0
Lost to Follow-up	0	0	1	0	1	1	0	0
Withdrawal by Subject	3	1	3	4	2	3	3	0
Noncompliance with protocol	1	0	0	0	0	0	0	0
Completed Treatment Phase	3	0	0	0	0	23	0	0

Period 2: Post-amendment 2

	Arm 1A: PEG + RBV	Arm 1B: PEG + RBV + BOC	Arm 2: PEG + BOC 100 (48 Weeks)	Arm 3: PEG + BOC 200 (48 Weeks)	Arm 5: PEG + RBV + BOC 400	ARM 4+6: PEG + BOC 400 (24 + 48 Weeks)	Arm 7: PEG + BOC 800	Arm 8: PEG + RBV + BOC 800
STARTED	0	0	0	0	0	0	0	143
COMPLETED	0	0	0	0	0	0	0	88
NOT COMPLETED	0	0	0	0	0	0	0	55
Adverse Event	0	0	0	0	0	0	0	20
Lack of Efficacy	0	0	0	0	0	0	0	24
Lost to follow-up/withdrawal by subject	0	0	0	0	0	0	0	11

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
Arm 1A: PEG + RBV OR Arm 1B: PEG + RBV + BOC 400	Arm 1A: A single dose of PEG was given first, followed 1 week later by PEG + RBV for 12 weeks. If participant was HCV-RNA negative, PEG + RBV was continued for another 36 weeks. Arm 1B: A single dose of PEG was given first, followed 1 week later by PEG + RBV for 12 weeks. If HCV-RNA was detectable, BOC 400 was added for another 36 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 2: PEG + BOC 100 (48 Weeks)	A single dose of PEG was given first, followed 1 week later by PEG + BOC 100 for 48 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 3: PEG + BOC 200 (48 Weeks)	A single dose of PEG was given first, followed 1 week later by PEG + BOC 200 for 48 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 5: PEG + RBV + BOC 400	A single dose of PEG was given first, followed 1 week later by PEG + RBV + BOC 400. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arms 4 + 6: PEG + BOC 400 (24 + 48 Weeks)	A single dose of PEG was given first, followed 1 week later by PEG + BOC (24 or 48 weeks). By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 7: PEG + BOC 800	A single dose of PEG was given first, followed 1 week later by PEG + BOC 800. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Total	Total of all reporting groups

Baseline Measures

	Arm 1A: PEG + RBV OR Arm 1B: PEG + RBV + BOC 400	Arm 2: PEG + BOC 100 (48 Weeks)	Arm 3: PEG + BOC 200 (48 Weeks)	Arm 5: PEG + RBV + BOC 400	Arms 4 + 6: PEG + BOC 400 (24 + 48 Weeks)	Arm 7: PEG + BOC 800	Total
Number of Participants [units: participants]	**49**	**48**	**49**	**49**	**97**	**65**	**357**
Age [units: years] Mean (Standard Deviation)	**48.9 (9.7)**	**51.6 (7.0)**	**48.6 (9.4)**	**48.2 (8.9)**	**49.2 (8.7)**	**50.4 (7.3)**	**49.5 (8.6)**
Gender [units: participants]							
Female	**17**	**21**	**14**	**21**	**37**	**24**	**134**
Male	**32**	**27**	**35**	**28**	**60**	**41**	**223**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percent of Participants Who Were Hepatitis C Virus Ribonucleic Acid (HCV-RNA) Negative at the End of Treatment (EoT) [Time Frame: Baseline up to Week 49]

Measure Type	Primary
Measure Title	Percent of Participants Who Were Hepatitis C Virus Ribonucleic Acid (HCV-RNA) Negative at the End of Treatment (EoT)
Measure Description	Sustained Viral Response (SVR) was defined as the percentage of participants with HCV-RNA undetectable at the follow-up Week 24. All percentages were based on the total number of participants originally randomized/enrolled to that particular arm. For Arm 1B, the denominator for the percentages was the number who received at least 1 dose of BOC. Arm 1A was not analyzed.
Time Frame	Baseline up to Week 49

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.
For PEG + RBV + BOC number of participants was number who received at least one dose of BOC. For all others, it was number of randomized participants. The PEG + BOC 800 arm was not randomized.

Reporting Groups

	Description
Arm 1B: PEG + RBV + BOC 400	A single dose of PEG was given first, followed 1 week later by PEG + RBV for 12 weeks. If HCV-RNA was detectable, BOC 400 was added for another 36 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 2: PEG + BOC 100 (48 Weeks)	A single dose of PEG was given first, followed 1 week later by PEG + BOC 100 for 48 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 3: PEG + BOC 200 (48 Weeks)	A single dose of PEG was given first, followed 1 week later by PEG + BOC 200 for 48 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arms 4 + 6: PEG + BOC 400 (24 + 48 Weeks)	A single dose of PEG was given first, followed 1 week later by PEG + BOC (24 or 48 weeks). By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 5: PEG + RBV + BOC 400	A single dose of PEG was given first, followed 1 week A single dose of PEG was given first, followed 1 week later by PEG + RBV + BOC 400. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 7: PEG + BOC 800	A single dose of PEG was given first, followed 1 week later by PEG + BOC 800. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.

Measured Values

	Arm 1B: PEG + RBV + BOC 400	**Arm 2: PEG + BOC 100 (48 Weeks)**	**Arm 3: PEG + BOC 200 (48 Weeks)**	**Arms 4 + 6: PEG + BOC 400 (24 + 48 Weeks)**	**Arm 5: PEG + RBV + BOC 400**	**Arm 7: PEG + BOC 800**
Number of Participants Analyzed [units: participants]	**40**	**48**	**49**	**97**	**49**	**65**
Percent of Participants Who Were Hepatitis C Virus Ribonucleic Acid (HCV-RNA) Negative at the End of Treatment (EoT) [units: Percent of participants]	**35.0**	**6.3**	**16.3**	**13.4**	**20.4**	**21.5**

No statistical analysis provided for Percent of Participants Who Were Hepatitis C Virus Ribonucleic Acid (HCV-RNA) Negative at the End of Treatment (EoT)

2. Primary: Percent of Participants Who Achieved Sustained Virologic Response (SVR) [Time Frame: Baseline up to Week 73 [24 weeks after end of treatment (EoT)]]

Measure Type	Primary
Measure Title	Percent of Participants Who Achieved Sustained Virologic Response (SVR)
Measure Description	SVR was defined as the percentage of participants with Hepatitis C Virus Ribonucleic Acid (HCV-RNA) undetectable at the follow-up Week 24. All percentages were based on the total number of participants originally randomized/enrolled to that particular arm. For Arm 1B, the denominator for the percentages was the number who received at least 1 dose of BOC. Arm 1A was not analyzed.
Time Frame	Baseline up to Week 73 [24 weeks after end of treatment (EoT)]
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.
For PEG + RBV + BOC number of participants was number who received at least one dose of BOC. For all others, it was number of randomized participants. The PEG + BOC 800 arm was not randomized.

Reporting Groups

	Description
Arm 1B: PEG + RBV + BOC 400	A single dose of PEG was given first, followed 1 week later by PEG + RBV for 12 weeks. If HCV-RNA was detectable, BOC 400 was added for another 36 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 2: PEG + BOC 100 (48 Weeks)	A single dose of PEG was given first, followed 1 week later by PEG + BOC 100 for 48 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 3: PEG + BOC 200 (48 Weeks)	A single dose of PEG was given first, followed 1 week later by PEG + BOC 200 for 48 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arms 4 + 6: PEG + BOC 400 (24 + 48 Weeks)	A single dose of PEG was given first, followed 1 week later by PEG + BOC (24 or 48 weeks). By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 5: PEG + RBV + BOC 400	A single dose of PEG was given first, followed 1 week A single dose of PEG was given first, followed 1 week later by PEG + RBV + BOC 400. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 7: PEG + BOC 800	A single dose of PEG was given first, followed 1 week later by PEG + BOC 800. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.

Measured Values

	Arm 1B: PEG + RBV + BOC 400	Arm 2: PEG + BOC 100 (48 Weeks)	Arm 3: PEG + BOC 200 (48 Weeks)	Arms 4 + 6: PEG + BOC 400 (24 + 48 Weeks)	Arm 5: PEG + RBV + BOC 400	Arm 7: PEG + BOC 800
Number of Participants Analyzed [units: participants]	**40**	**48**	**49**	**97**	**49**	**65**
Percent of Participants Who Achieved Sustained Virologic Response (SVR) [units: Percent of participants]	**7.5**	**2.1**	**12.2**	**5.2**	**14.3**	**4.6**

No statistical analysis provided for Percent of Participants Who Achieved Sustained Virologic Response (SVR)

3. Secondary: Percent of Participants Who Achieved Sustained Viral Response (SVR) by Time to First Negative HCV-RNA [Time Frame: Baseline up to Week 73 [24 weeks after EoT]]

Measure Type	Secondary
Measure Title	Percent of Participants Who Achieved Sustained Viral Response (SVR) by Time to First Negative HCV-RNA
Measure Description	Percentage of participants who became HCV-RNA undetectable within the first 13 weeks and subsequently became HCV-RNA positive were not considered negative for this analysis.
Time Frame	Baseline up to Week 73 [24 weeks after EoT]
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.
Number of participants across all treatment arms who achieved negative HCV-RNA

Reporting Groups

	Description
0 to ≤ 4 Weeks to First Negative HCV-RNA Group	Participants who achieved first negative HCV RNA within the first 4 weeks of treatment.
>4 to 8 Weeks to First Negative HCV-RNA Group	Participants who achieved first negative HCV RNA between weeks 4 to 8.
>8 to 12 Weeks to First Negative HCV-RNA Group	Participants who achieved first negative HCV RNA between weeks 8 to 12.
>12 to 36 Weeks to First Negative HCV-RNA Group	Participants who achieved first negative HCV RNA between weeks 12 to 36.

Measured Values

	0 to ≤ 4 Weeks to First Negative HCV-RNA	>4 to 8 Weeks to First Negative HCV-RNA	>8 to 12 Weeks to First Negative HCV-RNA	>12 to 36 Weeks to First Negative HCV-RNA

	Group	Group	Group	Group
Number of Participants Analyzed [units: participants]	**33**	**12**	**6**	**11**
Percent of Participants Who Achieved Sustained Viral Response (SVR) by Time to First Negative HCV-RNA [units: Percent of participants]	**58**	**33**	**33**	**0**

No statistical analysis provided for Percent of Participants Who Achieved Sustained Viral Response (SVR) by Time to First Negative HCV-RNA

4. Secondary: Percentage of Participants Who Were HCV-RNA Negative at EoT After Receiving 1 Week of Treatment With PegIntron (PEG) by Log Drop [Time Frame: Week 1 and Week 49]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Were HCV-RNA Negative at EoT After Receiving 1 Week of Treatment With PegIntron (PEG) by Log Drop
Measure Description	For each log drop category (<0, 0 to 0.5, 0.5 to <1, 1 to <1.5, ≥1.5, and Missing), the percentage of participants receiving combination therapy who were HCV-RNA negative at EoT (Week 49) was calculated as follows: Number of participants in a log category who were HCV-RNA negative divided by the total number of participants in that log drop category (n). Percentages were NOT derived using treatment arm N values. The sum of the n values for all 6 log drop categories within a treatment arm equals the overall N for that treatment group.
Time Frame	Week 1 and Week 49
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.
N=Number of Participants Analyzed, n=number of participants in each log category group. The PEG + BOC 100, 200, or 400 arm combined the following treatment arms: Arm 2 PEG + BOC 100 (48 weeks), Arm 3 PEG + BOC 200 (48 weeks), Arm 4 PEG + BOC 400 (48 weeks), Arm 6 PEG + BOC 400 (24 weeks).

Reporting Groups

	Description
Arms 2, 3, 4, 6: PEG + BOC 100, 200, or 400	A single dose of PEG was given first, followed 1 week later by PEG + BOC. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 5: PEG + RBV + BOC 400	A single dose of PEG was given first, followed 1 week later by PEG + RBV + BOC 400. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 7: PEG + BOC 800	A single dose of PEG was given first, followed 1 week later by PEG + BOC 800. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.

Measured Values

	Arms 2, 3, 4, 6: PEG + BOC 100, 200, or 400	Arm 5: PEG + RBV + BOC 400	Arm 7: PEG + BOC 800
Number of Participants Analyzed [units: participants]	**194**	**49**	**65**
Percentage of Participants Who Were HCV-RNA Negative at EoT After Receiving 1 Week of Treatment With PegIntron (PEG) by Log Drop [units: Percent of participants]			
Log drop <0 (Arm2-4,6 n=21/Arm5 n=6/Arm7 n=3)	**9.5**	**16.7**	**1**
Log drop 0-0.5 (Arm2-4,6 n=55/Arm5 n=17/Arm7 n=16)	**1.8**	**17.6**	**18.8**
Log drop 0.5to<1(Arm2-4,6 n=73/Arm5 n=11/Arm7 n=9)	**12.3**	**9.1**	**0**
Log drop 1to<1.5(Arm2-4,6 n=31/Arm5 n=9/Arm7 n=18)	**25.8**	**33.3**	**16.7**
Log drop ≥1.5 (Arm2-4,6 n=12/Arm5 n=4/Arm7 n=18)	**33.3**	**50.0**	**44.4**
Missing (Arm2-4,6 n=2/Arm5 n=2/Arm7 n=1)	**0**	**0**	**0**

No statistical analysis provided for Percentage of Participants Who Were HCV-RNA Negative at EoT After Receiving 1 Week of Treatment With PegIntron (PEG) by Log Drop

5. Secondary: Percent of Participants With Virologic Response Prior to Amendment 2 [Time Frame: Week 3, Week 5, Week 13]

Measure Type	Secondary
Measure Title	Percent of Participants With Virologic Response Prior to Amendment 2
Measure Description	Virologic response was defined as the percentage of participants with Hepatitis C Virus Ribonucleic Acid (HCV-RNA) ≤10,000 IU/mL.
Time Frame	Week 3, Week 5, Week 13
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.
No text entered.

Reporting Groups

	Description
Arm 1A: PEG + RBV and Arm 1B: PEG + RBV + BOC 400	Arm 1A: A single dose of PEG was given first, followed 1 week later by PEG + RBV for 12 weeks. If participant was HCV-RNA negative, PEG + RBV was continued for another 36 weeks. Arm 1B: A single dose of PEG was given first, followed 1 week later by PEG + RBV for 12 weeks. If HCV-RNA was detectable, BOC 400 was added for another 36 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 2: PEG + BOC 100 (48 Weeks)	A single dose of PEG was given first, followed 1 week later by PEG + BOC 100 for 48 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 3: PEG + BOC 200 (48 Weeks)	A single dose of PEG was given first, followed 1 week later by PEG + BOC 200 for 48 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 5: PEG + RBV + BOC 400	A single dose of PEG was given first, followed 1 week later by PEG + RBV + BOC 400. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arms 4 + 6: PEG + BOC 400 (24 + 48 Weeks)	A single dose of PEG was given first, followed 1 week later by PEG + BOC (24 or 48 weeks). By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 7: PEG + BOC 800	A single dose of PEG was given first, followed 1 week later by PEG + BOC 800. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.

Measured Values

	Arm 1A: PEG + RBV and Arm 1B: PEG + RBV + BOC 400	**Arm 2: PEG + BOC 100 (48 Weeks)**	**Arm 3: PEG + BOC 200 (48 Weeks)**	**Arm 5: PEG + RBV + BOC 400**	**Arms 4 + 6: PEG + BOC 400 (24 + 48 Weeks)**	**Arm 7: PEG + BOC 800**
Number of Participants Analyzed [units: participants]	**49**	**48**	**49**	**49**	**97**	**65**
Percent of Participants With Virologic Response Prior to Amendment 2 [units: Percent of participants]						
Week 3	**4.1**	**0.0**	**0.0**	**0**	**5.2**	**4.6**
Week 5	**4.1**	**0.0**	**8.2**	**12.2**	**9.3**	**15.4**
Week 13	**6.1**	**2.1**	**14.3**	**30.6**	**13.4**	**0**

No statistical analysis provided for Percent of Participants With Virologic Response Prior to Amendment 2

6. Secondary: Peak Plasma Concentration of Boceprevir (BOC) [Time Frame: All visits during treatment (baseline to Week 49) except Day 1 of Week 1]

Measure Type	Secondary
Measure Title	Peak Plasma Concentration of Boceprevir (BOC)
Measure Description	All plasma samples were assayed using a validated liquid chromatography with tandem mass spectrometric detection (LCMS/MS) method.
Time Frame	All visits during treatment (baseline to Week 49) except Day 1 of Week 1
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 were only included in the analysis if the recorded previous dose of boceprevir was taken < 8.5 hours prior to sample collection. Participants also must have started BOC treatment or amendment 2 dosing more than 1 week prior to sample collection.

Reporting Groups

	Description
BOC 100 mg Dose	A single dose of PEG was given first, followed 1 week later by Arm 2 (PEG + BOC 100). By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
BOC 200 mg Dose	A single dose of PEG was given first, followed 1 week later by Arm 3 (PEG + BOC 200). By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
BOC 400 mg Dose	A single dose of PEG was given first, followed 1 week later by Arms 1B, 4, 5, 6, or 7. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
BOC 800 mg Dose	A single dose of PEG was given first, followed 1 week later by PEG + BOC 800 or PEG + RBV + BOC 800. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.

Measured Values

	BOC 100 mg Dose	**BOC 200 mg Dose**	**BOC 400 mg Dose**	**BOC 800 mg Dose**
Number of Participants Analyzed [units: participants]	**29**	**24**	**62**	**64**
Peak Plasma Concentration of Boceprevir (BOC) [units: ng/mL] Mean (Standard Error)	**203 (5)**	**427 (18)**	**704 (16)**	**1312 (45)**

No statistical analysis provided for Peak Plasma Concentration of Boceprevir (BOC)

7. Secondary: Area Under the Plasma Concentration-time Curve of Boceprevir Plasma Concentration for an 8-hour Dosing Period [Time Frame: All visits during treatment (baseline to Week 49) except Day 1 of Week 1]

Measure Type	Secondary
Measure Title	Area Under the Plasma Concentration-time Curve of Boceprevir Plasma Concentration for an 8-hour Dosing Period
Measure Description	All plasma samples were assayed using a validated liquid chromatography with tandem mass spectrometric detection (LCMS/MS) method. The dosing interval of 8 hours is represented as the hr in the unit of measure.
Time Frame	All visits during treatment (baseline to Week 49) except Day 1 of Week 1
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 were only included in the analysis if the recorded previous dose of boceprevir was taken < 8.5 hours prior to sample collection. Participants also must have started BOC treatment or amendment 2 dosing more than 1 week prior to sample collection.

Reporting Groups

	Description
BOC 100 mg Dose	A single dose of PEG was given first, followed 1 week later by Arm 2 (PEG + BOC 100). By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
BOC 200 mg Dose	A single dose of PEG was given first, followed 1 week later by Arm 3 (PEG + BOC 200). By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
BOC 400 mg Dose	A single dose of PEG was given first, followed 1 week later by Arms 1B, 4, 5, 6, or 7. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
BOC 800 mg Dose	A single dose of PEG was given first, followed 1 week later by PEG + BOC 800 or PEG + RBV + BOC 800. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.

Measured Values

	BOC 100 mg Dose	BOC 200 mg Dose	BOC 400 mg Dose	BOC 800 mg Dose
Number of Participants Analyzed [units: participants]	**29**	**24**	**62**	**64**
Area Under the Plasma Concentration-time Curve of Boceprevir Plasma Concentration for an 8-hour Dosing Period [units: ng*hr/mL] Mean (Standard Error)	**1042 (25)**	**2184 (181)**	**3633 (88)**	**6276 (337)**

No statistical analysis provided for Area Under the Plasma Concentration-time Curve of Boceprevir Plasma Concentration for an 8-hour Dosing Period

8. Secondary: Trough Plasma Concentration Level [Time Frame: All visits during treatment (baseline to Week 49) except Day 1 of Week 1]

Measure Type	Secondary
Measure Title	Trough Plasma Concentration Level
Measure Description	All plasma samples were assayed using a validated liquid chromatography with tandem mass spectrometric detection (LCMS/MS) method.
Time Frame	All visits during treatment (baseline to Week 49) except Day 1 of Week 1
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 were only included in the analysis if the recorded previous dose of boceprevir was taken < 8.5 hours prior to sample collection. Participants also must have started BOC treatment or amendment 2 dosing more than 1 week prior to sample collection.

Reporting Groups

	Description
BOC 100 mg Dose	A single dose of PEG was given first, followed 1 week later by Arm 2 (PEG + BOC 100). By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
BOC 200 mg Dose	A single dose of PEG was given first, followed 1 week later by Arm 3 (PEG + BOC 200). By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
BOC 400 mg Dose	A single dose of PEG was given first, followed 1 week later by Arms 1B, 4, 5, 6, or 7. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
BOC 800 mg Dose	A single dose of PEG was given first, followed 1 week later by PEG + BOC 800 or PEG + RBV + BOC 800. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.

Measured Values

	BOC 100 mg Dose	BOC 200 mg Dose	BOC 400 mg Dose	BOC 800 mg Dose
Number of Participants Analyzed [units: participants]	**29**	**24**	**62**	**64**
Trough Plasma Concentration Level [units: ng/mL]	**56.7 (3)**	**133.0 (27)**	**214.0 (10)**	**355 (42)**

Mean (Standard Error)				

No statistical analysis provided for Trough Plasma Concentration Level

9. Secondary: Change in Alanine Aminotransferase (ALT) Levels [Time Frame: Baseline up to dosing change (> 25 weeks)]

Measure Type	Secondary
Measure Title	Change in Alanine Aminotransferase (ALT) Levels
Measure Description	Change in ALT levels during initial treatment regimen and after rolling into amendment 2 as compared to baseline.
Time Frame	Baseline up to dosing change (> 25 weeks)
Safety Issue	Yes

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.
Only participants with at least one value for the laboratory test were included.

Reporting Groups

	Description
Arm 1A: PEG + RBV	Arm 1A: A single dose of PEG was given first, followed 1 week later by PEG + RBV for 12 weeks. If participant was HCV-RNA negative, PEG + RBV was continued for another 36 weeks.
Arm 1B: PEG + RBV + BOC 400	Arm 1B: A single dose of PEG was given first, followed 1 week later by PEG + RBV for 12 weeks. If HCV-RNA was detectable, BOC 400 was added for another 36 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 2: PEG + BOC 100 (48 Weeks)	A single dose of PEG was given first, followed 1 week later by PEG + BOC 100 for 48 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 3: PEG + BOC 200	A single dose of PEG was given first, followed 1 week later by PEG + BOC 200 for 48 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 5: PEG + RBV + BOC 400	A single dose of PEG was given first, followed 1 week later by PEG + RBV + BOC 400. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arms 4 + 6: PEG + BOC 400 (24 + 48 Weeks)	A single dose of PEG was given first, followed 1 week later by PEG + BOC (24 or 48 weeks). By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 7: PEG + BOC 800	A single dose of PEG was given first, followed 1 week later by PEG + BOC 800. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
Arm 8: PEG + RBV + BOC 800	By protocol amendment 2, participants from all arms except Arm 1A were rolled over into PEG + RBV + BOC 800 for the remainder of the treatment period.

Measured Values

	Arm 1A: PEG + RBV	**Arm 1B: PEG + RBV + BOC 400**	**Arm 2: PEG + BOC 100 (48 Weeks)**	**Arm 3: PEG + BOC 200**	**Arm 5: PEG + RBV + BOC 400**	**Arms 4 + 6: PEG + BOC 400 (24 + 48 Weeks)**	**Arm 7: PEG + BOC 800**	**Arm 8: PEG + RBV + BOC 800**
Number of Participants Analyzed [units: participants]	**15**	**34**	**48**	**47**	**48**	**97**	**64**	**143**
Change in Alanine Aminotransferase (ALT) Levels [units: Participants]								
<2.00 x baseline ALT value	**14**	**33**	**45**	**43**	**47**	**84**	**61**	**119**
2.00-2.09 x baseline ALT value	**1**	**1**	**1**	**1**	**0**	**4**	**0**	**4**
2.10-5.09 x baseline ALT value	**0**	**0**	**2**	**3**	**1**	**9**	**3**	**18**
5.10-10.0 x baseline								

ALT value	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**
>10.0 x baseline ALT value	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**

No statistical analysis provided for Change in Alanine Aminotransferase (ALT) Levels

10. Secondary: Number of Participants Who Were HCV-RNA Negative During Amendment 2 (AM2) for Those Who Started on Arms 2 (PEG+BOC 100), 3 (PEG+BOC 200), 4 (PEG+BOC 400 [48 Weeks]), 6 (PEG+BOC 400 [24 Weeks]) [Time Frame: From dosing change to end of follow-up (Week 73)(up to 48 weeks)]

Measure Type	Secondary
Measure Title	Number of Participants Who Were HCV-RNA Negative During Amendment 2 (AM2) for Those Who Started on Arms 2 (PEG+BOC 100), 3 (PEG+BOC 200), 4 (PEG+BOC 400 [48 Weeks]), 6 (PEG+BOC 400 [24 Weeks])
Measure Description	Log drop at baseline of dosing change = difference of log viral loads between baseline (closest to the treatment begin date) and dosing change baseline (virology value closest to the dosing change begin date).
Time Frame	From dosing change to end of follow-up (Week 73)(up to 48 weeks)
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.
All participants, per the second amendment to P03659, with significant HCV-RNA decrease (HCV_RNA ≤ 10,000 IU) switched to continuing triple therapy.

Reporting Groups

	Description
Log Drop 0 to <1	All arms were given single dose of PEG first, followed 1 week later by PEG + BOC 100 for 48 weeks for Arm 2 (PEG+BOC 100), followed by PEG + BOC 200 for 48 weeks for Arm 3 (PEG+BOC 200), followed by PEG + BOC (24 or 48 weeks) for Arm 4 (PEG+BOC 400 [48 weeks]) and Arm 6 (PEG+BOC 400 [24 weeks]). By protocol amendment 2, participants were switched to an increased dose of BOC 800 TID plus RBV with PEG for an additional 24 Weeks of Treatment.
Log Drop 1 to <2	All arms were given single dose of PEG first, followed 1 week later by PEG + BOC 100 for 48 weeks for Arm 2 (PEG+BOC 100), followed by PEG + BOC 200 for 48 weeks for Arm 3 (PEG+BOC 200), followed by PEG + BOC (24 or 48 weeks) for Arm 4 (PEG+BOC 400 [48 weeks]) and Arm 6 (PEG+BOC 400 [24 weeks]). By protocol amendment 2, participants were switched to an increased dose of BOC 800 TID plus RBV with PEG for an additional 24 Weeks of Treatment.
Log Drop 2 to <3	All arms were given single dose of PEG first, followed 1 week later by PEG + BOC 100 for 48 weeks for Arm 2 (PEG+BOC 100), followed by PEG + BOC 200 for 48 weeks for Arm 3 (PEG+BOC 200), followed by PEG + BOC (24 or 48 weeks) for Arm 4 (PEG+BOC 400 [48 weeks]) and Arm 6 (PEG+BOC 400 [24 weeks]). By protocol amendment 2, participants were switched to an increased dose of BOC 800 TID plus RBV with PEG for an additional 24 Weeks of Treatment.
Log Drop 3 to <4	All arms were given single dose of PEG first, followed 1 week later by PEG + BOC 100 for 48 weeks for Arm 2 (PEG+BOC 100), followed by PEG + BOC 200 for 48 weeks for Arm 3 (PEG+BOC 200), followed by PEG + BOC (24 or 48 weeks) for Arm 4 (PEG+BOC 400 [48 weeks]) and Arm 6 (PEG+BOC 400 [24 weeks]). By protocol amendment 2, participants were switched to an increased dose of BOC 800 TID plus RBV with PEG for an additional 24 Weeks of Treatment.
Log Drop 4 to <5	All arms were given single dose of PEG first, followed 1 week later by PEG + BOC 100 for 48 weeks for Arm 2 (PEG+BOC 100), followed by PEG + BOC 200 for 48 weeks for Arm 3 (PEG+BOC 200), followed by PEG + BOC (24 or 48 weeks) for Arm 4 (PEG+BOC 400 [48 weeks]) and Arm 6 (PEG+BOC 400 [24 weeks]). By protocol amendment 2, participants were switched to an increased dose of BOC 800 TID plus RBV with PEG for an additional 24 Weeks of Treatment.
Log Drop ≥5	All arms were given single dose of PEG first, followed 1 week later by PEG + BOC 100 for 48 weeks for Arm 2 (PEG+BOC 100), followed by PEG + BOC 200 for 48 weeks for Arm 3 (PEG+BOC 200), followed by PEG + BOC (24 or 48 weeks) for Arm 4 (PEG+BOC 400 [48 weeks]) and Arm 6 (PEG+BOC 400 [24 weeks]). By protocol amendment 2, participants were switched to an increased dose of BOC 800 TID plus RBV with PEG for an additional 24 Weeks of Treatment.

Measured Values

	Log Drop 0 to <1	**Log Drop 1 to <2**	**Log Drop 2 to <3**	**Log Drop 3 to <4**	**Log Drop 4 to <5**	**Log Drop ≥5**
Number of Participants Analyzed [units: participants]	**4**	**2**	**2**	**4**	**12**	**3**
Number of Participants Who Were HCV-RNA Negative During Amendment 2 (AM2) for Those Who Started on Arms 2 (PEG+BOC 100), 3 (PEG+BOC 200), 4 (PEG+BOC 400 [48 Weeks]), 6 (PEG+BOC						

400 [24 Weeks]) [units: Participants]						
Week 3 after dosing change	**0**	**0**	**0**	**4**	**11**	**2**
Week 6 after dosing change	**0**	**0**	**0**	**4**	**11**	**1**
Week 9 after dosing change	**0**	**0**	**0**	**4**	**9**	**1**
Week 12 after dosing change	**0**	**0**	**0**	**4**	**9**	**1**
Week 18 after dosing change	**1**	**0**	**1**	**4**	**11**	**1**
Week 24 after dosing change	**1**	**0**	**1**	**4**	**12**	**1**
End of treatment	**1**	**0**	**1**	**4**	**11**	**1**
Follow-up Week 4 after dosing change	**0**	**0**	**0**	**4**	**8**	**1**
Follow-up Week 8 after dosing change	**0**	**0**	**0**	**4**	**6**	**1**
Follow-up Week 12 after dosing change	**0**	**0**	**0**	**4**	**6**	**1**
Follow-up Week 24 after dosing change	**0**	**0**	**0**	**4**	**7**	**1**
End of follow-up after dosing change	**0**	**0**	**0**	**4**	**7**	**1**

No statistical analysis provided for Number of Participants Who Were HCV-RNA Negative During Amendment 2 (AM2) for Those Who Started on Arms 2 (PEG+BOC 100), 3 (PEG+BOC 200), 4 (PEG+BOC 400 [48 Weeks]), 6 (PEG+BOC 400 [24 Weeks])

11. Secondary: Number of Participants Who Were HCV-RNA Negative During Amendment 2 (AM2) for Those Who Started on PegIntron (PEG) + Rebetol (RVB) + Boceprevir (BOC) 400 (Arm 5) [Time Frame: From dosing change to end of follow-up (Week 73)(up to 48 weeks)]

Measure Type	Secondary
Measure Title	Number of Participants Who Were HCV-RNA Negative During Amendment 2 (AM2) for Those Who Started on PegIntron (PEG) + Rebetol (RVB) + Boceprevir (BOC) 400 (Arm 5)
Measure Description	Log drop at baseline of dosing change = difference of log viral loads between baseline (closest to the treatment begin date) and dosing change baseline (virology value closest to the dosing change begin date).
Time Frame	From dosing change to end of follow-up (Week 73)(up to 48 weeks)
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.
All participants, per the second amendment to P03659, with significant HCV-RNA decrease (HCV_RNA ≤ 10,000 IU) switched to continuing triple therapy.

Reporting Groups

	Description
Log Drop 1 to <2	Arm 5: A single dose of PEG first, followed 1 week later by PEG + RBV + BOC 400 for 48 weeks. By protocol amendment 2, participants were switched to an increased dose of BOC 800 plus RBV with PEG for an additional 24 Weeks of Treatment.
Log Drop 2 to <3	Arm 5: A single dose of PEG first, followed 1 week later by PEG + RBV + BOC 400 for 48 weeks. By protocol amendment 2, participants were switched to an increased dose of BOC 800 plus RBV with PEG for an additional 24 Weeks of Treatment.
Log Drop 3 to <4	Arm 5: A single dose of PEG first, followed 1 week later by PEG + RBV + BOC 400 for 48 weeks. By protocol amendment 2, participants were switched to an increased dose of BOC 800 plus RBV with PEG for an additional 24 Weeks of Treatment.
Log Drop 4 to <5	Arm 5: A single dose of PEG first, followed 1 week later by PEG + RBV + BOC 400 for 48 weeks. By protocol amendment 2, participants were switched to an increased dose of BOC 800 plus RBV with PEG for an additional 24 Weeks of Treatment.
Log Drop ≥5	Arm 5: A single dose of PEG first, followed 1 week later by PEG + RBV + BOC 400 for 48 weeks. By protocol amendment 2, participants were switched to an increased dose of BOC 800 plus RBV with PEG for an additional 24 Weeks of Treatment.

Measured Values

	Log Drop 1 to <2	**Log Drop 2 to <3**	**Log Drop 3 to <4**	**Log Drop 4 to <5**	**Log Drop ≥5**
Number of Participants Analyzed [units: participants]	**1**	**1**	**4**	**14**	**1**

Number of Participants Who Were HCV-RNA Negative During Amendment 2 (AM2) for Those Who Started on PegIntron (PEG) + Rebetol (RVB) + Boceprevir (BOC) 400 (Arm 5) [units: Participants]					
Week 3 after dosing change	0	0	3	12	1
Week 6 after dosing change	0	0	3	10	0
Week 9 after dosing change	0	0	3	10	0
Week 12 after dosing change	0	0	3	9	0
Week 18 after dosing change	0	0	2	6	0
Week 24 after dosing change	0	0	3	5	0
End of treatment	0	0	3	7	0
Follow-up Week 4 after dosing change	0	0	3	6	0
Follow-up Week 8 after dosing change	0	0	3	4	0
Follow-up Week 12 after dosing change	0	0	2	5	0
Follow-up Week 24 after dosing change	0	0	3	4	0
End of follow-up after dosing change	0	0	3	4	0

No statistical analysis provided for Number of Participants Who Were HCV-RNA Negative During Amendment 2 (AM2) for Those Who Started on PegIntron (PEG) + Rebetol (RVB) + Boceprevir (BOC) 400 (Arm 5)

12. Secondary: Number of Participants Who Were HCV-RNA Negative During Amendment 2 (AM2) for Those Who Started on PegIntron (PEG) + Boceprevir (BOC) 800 (Arm 7) [Time Frame: From dosing change to end of follow-up (Week 73) (up to 48 weeks)]

Measure Type	Secondary
Measure Title	Number of Participants Who Were HCV-RNA Negative During Amendment 2 (AM2) for Those Who Started on PegIntron (PEG) + Boceprevir (BOC) 800 (Arm 7)
Measure Description	Log drop at baseline of dosing change = difference of log viral loads between baseline (closest to the treatment begin date) and dosing change baseline (virology value closest to the dosing change begin date).
Time Frame	From dosing change to end of follow-up (Week 73) (up to 48 weeks)
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.
All participants, per the second amendment to P03659, with significant HCV-RNA decrease (HCV_RNA ≤ 10,000 IU) switched to continuing triple therapy.

Reporting Groups

	Description
Log Drop <0	Arm 7: A single dose of PEG was given first, followed 1 week later by PEG + BOC 800. By protocol amendment 2, participants were switched to PEG + RBV + BOC 800 for an additional 24 Weeks of Treatment.
Log Drop 0 to <1	Arm 7: A single dose of PEG was given first, followed 1 week later by PEG + BOC 800. By protocol amendment 2, participants were switched to PEG + RBV + BOC 800 for an additional 24 Weeks of Treatment.
Log Drop 1 to <2	Arm 7: A single dose of PEG was given first, followed 1 week later by PEG + BOC 800. By protocol amendment 2, participants were switched to PEG + RBV + BOC 800 for an additional 24 Weeks of Treatment.
Log Drop 2 to <3	Arm 7: A single dose of PEG was given first, followed 1 week later by PEG + BOC 800. By protocol amendment 2, participants were switched to PEG + RBV + BOC 800 for an additional 24 Weeks of Treatment.
Log Drop 3 to <4	Arm 7: A single dose of PEG was given first, followed 1 week later by PEG + BOC 800. By protocol amendment 2, participants were switched to PEG + RBV + BOC 800 for an additional 24 Weeks of Treatment.
Log Drop 4 to <5	Arm 7: A single dose of PEG was given first, followed 1 week later by PEG + BOC 800. By protocol amendment 2, participants were switched to PEG + RBV + BOC 800 for an additional 24 Weeks of Treatment.
Log Drop ≥5	Arm 7: A single dose of PEG was given first, followed 1 week later by PEG + BOC 800. By protocol amendment 2, participants were switched to PEG + RBV + BOC 800 for an additional 24 Weeks of Treatment.
Missing Data	Arm 7: A single dose of PEG was given first, followed 1 week later by PEG + BOC 800. By protocol amendment 2, participants were switched to PEG + RBV + BOC 800 for an additional 24 Weeks of Treatment.

Measured Values

	Log Drop <0	Log Drop 0 to <1	Log Drop 1 to <2	Log Drop 2 to <3	Log Drop 3 to <4	Log Drop 4 to <5	Log Drop ≥5	Missing Data
Number of Participants Analyzed [units: participants]	2	12	12	5	10	9	6	5
Number of Participants Who Were HCV-RNA Negative During Amendment 2 (AM2) for Those Who Started on PegIntron (PEG) + Boceprevir (BOC) 800 (Arm 7) [units: Participants]								
Week 3 after dosing change	0	0	0	0	5	7	4	3
Week 6 after dosing change	0	0	0	0	3	5	4	1
Week 9 after dosing change	0	0	0	0	5	7	3	1
Week 12 after dosing change	0	0	0	1	4	5	4	2
Week 18 after dosing change	0	0	0	1	5	3	4	2
Week 24 after dosing change	0	0	1	1	4	3	4	1
End of treatment	0	0	1	1	4	3	4	1
Follow-up Week 4 after dosing change	0	0	0	0	1	2	1	0
Follow-up Week 8 after dosing change	0	0	0	0	1	0	0	0
Follow-up Week 12 after dosing change	0	0	0	0	1	1	1	0
Follow-up Week 24 after dosing change	0	0	0	0	1	1	1	0
End of follow-up after dosing change	0	0	0	0	1	1	1	0

No statistical analysis provided for Number of Participants Who Were HCV-RNA Negative During Amendment 2 (AM2) for Those Who Started on PegIntron (PEG) + Boceprevir (BOC) 800 (Arm 7)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
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Reporting Groups

	Description
PEG + RBV	Arm 1A: A single dose of PEG was given first, followed 1 week later by PEG + RBV for 12 weeks. If participant was HCV-RNA negative, PEG + RBV was continued for another 36 weeks.
PEG + RBV + BOC 400 (24 Weeks)	Arm 1B: A single dose of PEG was given first, followed 1 week later by PEG + RBV for 12 weeks. If HCV-RNA was detectable, BOC 400 was added for another 36 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
PEG + BOC 100 (48 Weeks)	Arm 2: A single dose of PEG was given first, followed 1 week later by PEG + BOC 100 for 48 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
PEG + BOC 200 (48 Weeks)	Arm 3: A single dose of PEG was given first, followed 1 week later by PEG + BOC 200 for 48 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
PEG + RBV + BOC 400 (48 Weeks)	Arm 5: A single dose of PEG was given first, followed 1 week later by PEG + RBV + BOC 400. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
PEG + BOC 400 (24 + 48 Weeks)	Arms 4 + 6: A single dose of PEG was given first, followed 1 week later by PEG + BOC (24 or 48 weeks). By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
PEG + BOC 800 (24 Weeks)	Arm 7: A single dose of PEG was given first, followed 1 week later by PEG + BOC 800. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
PEG + RBV + BOC 800	Arm 8: By protocol amendment 2, participants from all arms except Arm 1A were rolled over into PEG + RBV + BOC 800 for the remainder of the treatment period.

Serious Adverse Events

	PEG + RBV	PEG + RBV + BOC 400 (24 Weeks)	PEG + BOC 100 (48 Weeks)	PEG + BOC 200 (48 Weeks)	PEG + RBV + BOC 400 (48 Weeks)	PEG + BOC 400 (24 + 48 Weeks)	PEG + BOC 800 (24 Weeks)	PEG + RBV + BOC 800
Total, serious adverse events								
# participants affected / at risk	2/15 (13.33%)	1/34 (2.94%)	2/48 (4.17%)	4/49 (8.16%)	2/49 (4.08%)	4/97 (4.12%)	3/65 (4.62%)	12/143 (8.39%)
Blood and lymphatic system disorders								
ANAEMIA † [1]								
# participants affected / at risk	0/15 (0.00%)	1/34 (2.94%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	0	1	0	0	0	0	0	0
Cardiac disorders								
MYOCARDIAL INFARCTION † [1]								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	1/143 (0.70%)
# events	0	0	0	0	0	0	0	1
Gastrointestinal disorders								
ABDOMINAL PAIN † [1]								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	1/48 (2.08%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	0	0	1	0	0	0	0	0
ABDOMINAL PAIN UPPER † [1]								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	1/49 (2.04%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	0	0	0	1	0	0	0	0
ALCOHOLIC PANCREATITIS † [1]								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	1/97 (1.03%)	0/65 (0.00%)	0/143 (0.00%)
# events	0	0	0	0	0	1	0	0
DIARRHOEA † [1]								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	2/65 (3.08%)	0/143 (0.00%)
# events	0	0	0	0	0	0	2	0
NAUSEA † [1]								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	1/65 (1.54%)	0/143 (0.00%)
# events	0	0	0	0	0	0	1	0
VOMITING † [1]								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	1/65 (1.54%)	1/143 (0.70%)
# events	0	0	0	0	0	0	1	1
General disorders								
CHEST PAIN † [1]								
# participants	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	1/49 (2.04%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	3/143 (2.10%)

affected / at risk								
# events	0	0	0	1	0	0	0	3
Hepatobiliary disorders								
CHOLECYSTITIS ACUTE † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	1/143 (0.70%)
# events	0	0	0	0	0	0	0	1
CHOLELITHIASIS † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	1/143 (0.70%)
# events	0	0	0	0	0	0	0	1
CHRONIC HEPATIC FAILURE † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	1/143 (0.70%)
# events	0	0	0	0	0	0	0	1
Infections and infestations								
APPENDICITIS † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	1/49 (2.04%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	0	0	0	1	0	0	0	0
GASTROENTERITIS † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	1/48 (2.08%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	0	0	1	0	0	0	0	0
MASTOIDITIS † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	1/143 (0.70%)
# events	0	0	0	0	0	0	0	1
URINARY TRACT INFECTION † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	1/65 (1.54%)	0/143 (0.00%)
# events	0	0	0	0	0	0	1	0
Injury, poisoning and procedural complications								
CONTUSION † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	1/49 (2.04%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	0	0	0	0	1	0	0	0
Metabolism and nutrition disorders								
FOOD INTOLERANCE † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	1/49 (2.04%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	0	0	0	1	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
BLADDER NEOPLASM † 1								

# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	1	0	0	0	0	0	0	0
HEPATIC NEOPLASM MALIGNANT † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	2/143 (1.40%)
# events	0	0	0	0	0	0	0	3
SQUAMOUS CELL CARCINOMA † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	1/97 (1.03%)	0/65 (0.00%)	0/143 (0.00%)
# events	0	0	0	0	0	1	0	0
Nervous system disorders								
CERVICOBRACHIAL SYNDROME † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	1/143 (0.70%)
# events	0	0	0	0	0	0	0	1
CONVULSION † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	0/48 (0.00%)	1/49 (2.04%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	1	0	0	1	0	0	0	0
RADIAL NERVE PALSY † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	1/97 (1.03%)	0/65 (0.00%)	0/143 (0.00%)
# events	0	0	0	0	0	1	0	0
SYNCOPE † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	1/49 (2.04%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	1/143 (0.70%)
# events	0	0	0	1	0	0	0	1
Reproductive system and breast disorders								
ENDOMETRIOSIS † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	1/97 (1.03%)	0/65 (0.00%)	0/143 (0.00%)
# events	0	0	0	0	0	1	0	0
PROSTATITIS † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	1/65 (1.54%)	0/143 (0.00%)
# events	0	0	0	0	0	0	1	0
Respiratory, thoracic and mediastinal disorders								
ASTHMA † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	1/49 (2.04%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	0	0	0	0	1	0	0	0
PLEURISY † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	1/48 (2.08%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	0	0	1	0	0	0	0	0

PULMONARY EMBOLISM † 1								
# participants affected / at risk	**0/15 (0.00%)**	**0/34 (0.00%)**	**0/48 (0.00%)**	**0/49 (0.00%)**	**0/49 (0.00%)**	**0/97 (0.00%)**	**0/65 (0.00%)**	**1/143 (0.70%)**
# events	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**
Surgical and medical procedures								
LIVER TRANSPLANT † 1								
# participants affected / at risk	**0/15 (0.00%)**	**0/34 (0.00%)**	**0/48 (0.00%)**	**0/49 (0.00%)**	**0/49 (0.00%)**	**0/97 (0.00%)**	**0/65 (0.00%)**	**1/143 (0.70%)**
# events	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**
Vascular disorders								
HYPERTENSIVE CRISIS † 1								
# participants affected / at risk	**1/15 (6.67%)**	**0/34 (0.00%)**	**0/48 (0.00%)**	**0/49 (0.00%)**	**0/49 (0.00%)**	**0/97 (0.00%)**	**0/65 (0.00%)**	**0/143 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 10.0

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	Arm 1A: A single dose of PEG was given first, followed 1 week later by PEG + RBV for 12 weeks. If participant was HCV-RNA negative, PEG + RBV was continued for another 36 weeks.
PEG + RBV + BOC 400 (24 Weeks)	Arm 1B: A single dose of PEG was given first, followed 1 week later by PEG + RBV for 12 weeks. If HCV-RNA was detectable, BOC 400 was added for another 36 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
PEG + BOC 100 (48 Weeks)	Arm 2: A single dose of PEG was given first, followed 1 week later by PEG + BOC 100 for 48 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
PEG + BOC 200 (48 Weeks)	Arm 3: A single dose of PEG was given first, followed 1 week later by PEG + BOC 200 for 48 weeks. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
PEG + RBV + BOC 400 (48 Weeks)	Arm 5: A single dose of PEG was given first, followed 1 week later by PEG + RBV + BOC 400. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
PEG + BOC 400 (24 + 48 Weeks)	Arms 4 + 6: A single dose of PEG was given first, followed 1 week later by PEG + BOC (24 or 48 weeks). By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
PEG + BOC 800 (24 Weeks)	Arm 7: A single dose of PEG was given first, followed 1 week later by PEG + BOC 800. By protocol amendment 2, participants were rolled over into Arm 8 for the remainder of the treatment period.
PEG + RBV + BOC 800	Arm 8: By protocol amendment 2, participants from all arms except Arm 1A were rolled over into PEG + RBV + BOC 800 for the remainder of the treatment period.

Other Adverse Events

	PEG + RBV	PEG + RBV + BOC 400 (24 Weeks)	PEG + BOC 100 (48 Weeks)	PEG + BOC 200 (48 Weeks)	PEG + RBV + BOC 400 (48 Weeks)	PEG + BOC 400 (24 + 48 Weeks)	PEG + BOC 800 (24 Weeks)	PEG + RBV + BOC 800

Total, other (not including serious) adverse events								
# participants affected / at risk	**14/15 (93.33%)**	**33/34 (97.06%)**	**48/48 (100.00%)**	**48/49 (97.96%)**	**47/49 (95.92%)**	**96/97 (98.97%)**	**64/65 (98.46%)**	**136/143 (95.10%)**
Blood and lymphatic system disorders								
ANAEMIA † 1								
# participants affected / at risk	**1/15 (6.67%)**	**4/34 (11.76%)**	**1/48 (2.08%)**	**0/49 (0.00%)**	**8/49 (16.33%)**	**1/97 (1.03%)**	**2/65 (3.08%)**	**54/143 (37.76%)**
# events	**1**	**5**	**1**	**0**	**12**	**1**	**2**	**58**
LEUKOPENIA † 1								
# participants affected / at risk	**1/15 (6.67%)**	**0/34 (0.00%)**	**1/48 (2.08%)**	**1/49 (2.04%)**	**2/49 (4.08%)**	**2/97 (2.06%)**	**0/65 (0.00%)**	**7/143 (4.90%)**
# events	**2**	**0**	**1**	**1**	**4**	**6**	**0**	**13**
NEUTROPENIA † 1								
# participants affected / at risk	**3/15 (20.00%)**	**3/34 (8.82%)**	**5/48 (10.42%)**	**5/49 (10.20%)**	**9/49 (18.37%)**	**12/97 (12.37%)**	**9/65 (13.85%)**	**25/143 (17.48%)**
# events	**4**	**3**	**7**	**5**	**16**	**20**	**10**	**37**
SPLENOMEGALY † 1								
# participants affected / at risk	**0/15 (0.00%)**	**1/34 (2.94%)**	**3/48 (6.25%)**	**1/49 (2.04%)**	**1/49 (2.04%)**	**1/97 (1.03%)**	**1/65 (1.54%)**	**1/143 (0.70%)**
# events	**0**	**1**	**3**	**1**	**1**	**1**	**1**	**1**
THROMBOCYTOPENIA † 1								
# participants affected / at risk	**0/15 (0.00%)**	**0/34 (0.00%)**	**2/48 (4.17%)**	**2/49 (4.08%)**	**2/49 (4.08%)**	**5/97 (5.15%)**	**0/65 (0.00%)**	**2/143 (1.40%)**
# events	**0**	**0**	**2**	**2**	**2**	**5**	**0**	**3**
Cardiac disorders								
PALPITATIONS † 1								
# participants affected / at risk	**1/15 (6.67%)**	**2/34 (5.88%)**	**1/48 (2.08%)**	**0/49 (0.00%)**	**1/49 (2.04%)**	**2/97 (2.06%)**	**0/65 (0.00%)**	**5/143 (3.50%)**
# events	**1**	**2**	**1**	**0**	**1**	**2**	**0**	**6**
Ear and labyrinth disorders								
EAR DISCOMFORT † 1								
# participants affected / at risk	**0/15 (0.00%)**	**0/34 (0.00%)**	**3/48 (6.25%)**	**0/49 (0.00%)**	**3/49 (6.12%)**	**2/97 (2.06%)**	**0/65 (0.00%)**	**2/143 (1.40%)**
# events	**0**	**0**	**3**	**0**	**3**	**3**	**0**	**2**
TINNITUS † 1								
# participants affected / at risk	**0/15 (0.00%)**	**1/34 (2.94%)**	**4/48 (8.33%)**	**0/49 (0.00%)**	**4/49 (8.16%)**	**0/97 (0.00%)**	**0/65 (0.00%)**	**0/143 (0.00%)**
# events	**0**	**1**	**4**	**0**	**4**	**0**	**0**	**0**
VERTIGO † 1								
# participants affected / at risk	**1/15 (6.67%)**	**1/34 (2.94%)**	**1/48 (2.08%)**	**1/49 (2.04%)**	**2/49 (4.08%)**	**0/97 (0.00%)**	**0/65 (0.00%)**	**1/143 (0.70%)**
# events	**1**	**1**	**1**	**1**	**3**	**0**	**0**	**1**
Endocrine disorders								
HYPERTHYROIDISM † 1								
# participants affected / at risk	**1/15 (6.67%)**	**0/34 (0.00%)**	**1/48 (2.08%)**	**0/49 (0.00%)**	**0/49 (0.00%)**	**0/97 (0.00%)**	**0/65 (0.00%)**	**1/143 (0.70%)**
# events	**1**	**0**	**1**	**0**	**0**	**0**	**0**	**1**
HYPOTHYROIDISM † 1								
# participants affected / at risk	**1/15 (6.67%)**	**0/34 (0.00%)**	**1/48 (2.08%)**	**0/49 (0.00%)**	**1/49 (2.04%)**	**4/97 (4.12%)**	**3/65 (4.62%)**	**6/143 (4.20%)**
# events	**1**	**0**	**1**	**0**	**1**	**4**	**3**	**8**
Eye disorders								
DRY EYE † 1								
# participants affected /	**2/15 (13.33%)**							

at risk		2/34 (5.88%)	1/48 (2.08%)	0/49 (0.00%)	1/49 (2.04%)	3/97 (3.09%)	0/65 (0.00%)	1/143 (0.70%)
# events	2	2	1	0	1	3	0	1
EYE IRRITATION † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	2/97 (2.06%)	0/65 (0.00%)	0/143 (0.00%)
# events	1	0	0	0	0	2	0	0
EYE PRURITUS † 1								
# participants affected / at risk	1/15 (6.67%)	1/34 (2.94%)	0/48 (0.00%)	1/49 (2.04%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	1	1	0	1	0	0	0	0
LACRIMATION INCREASED † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	1/49 (2.04%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	1	0	0	0	1	0	0	0
VISION BLURRED † 1								
# participants affected / at risk	1/15 (6.67%)	1/34 (2.94%)	1/48 (2.08%)	0/49 (0.00%)	2/49 (4.08%)	4/97 (4.12%)	2/65 (3.08%)	3/143 (2.10%)
# events	1	1	1	0	2	4	2	3
VISUAL ACUITY REDUCED † 1								
# participants affected / at risk	0/15 (0.00%)	2/34 (5.88%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	1/65 (1.54%)	2/143 (1.40%)
# events	0	2	0	0	0	0	1	2
Gastrointestinal disorders								
ABDOMINAL DISTENSION † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	4/48 (8.33%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	1/65 (1.54%)	0/143 (0.00%)
# events	0	0	4	0	0	0	1	0
ABDOMINAL PAIN † 1								
# participants affected / at risk	0/15 (0.00%)	2/34 (5.88%)	4/48 (8.33%)	2/49 (4.08%)	4/49 (8.16%)	5/97 (5.15%)	3/65 (4.62%)	4/143 (2.80%)
# events	0	2	5	3	4	6	3	4
ABDOMINAL PAIN UPPER † 1								
# participants affected / at risk	1/15 (6.67%)	4/34 (11.76%)	9/48 (18.75%)	9/49 (18.37%)	5/49 (10.20%)	17/97 (17.53%)	1/65 (1.54%)	11/143 (7.69%)
# events	1	4	12	13	6	21	1	14
CONSTIPATION † 1								
# participants affected / at risk	0/15 (0.00%)	2/34 (5.88%)	1/48 (2.08%)	4/49 (8.16%)	1/49 (2.04%)	3/97 (3.09%)	1/65 (1.54%)	8/143 (5.59%)
# events	0	3	1	4	1	3	1	10
DIARRHOEA † 1								
# participants affected / at risk	6/15 (40.00%)	7/34 (20.59%)	11/48 (22.92%)	11/49 (22.45%)	10/49 (20.41%)	29/97 (29.90%)	21/65 (32.31%)	13/143 (9.09%)
# events	9	8	14	13	16	41	23	14
DRY MOUTH † 1								
# participants affected / at risk	1/15 (6.67%)	3/34 (8.82%)	0/48 (0.00%)	2/49 (4.08%)	3/49 (6.12%)	7/97 (7.22%)	3/65 (4.62%)	5/143 (3.50%)
# events	1	3	0	3	3	8	3	5
DYSPEPSIA † 1								
# participants affected / at risk	1/15 (6.67%)	2/34 (5.88%)	5/48 (10.42%)	2/49 (4.08%)	5/49 (10.20%)	6/97 (6.19%)	2/65 (3.08%)	4/143 (2.80%)
# events	1	3	5	2	5	6	2	6
FLATULENCE † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	2/48 (4.17%)	2/49 (4.08%)	3/49 (6.12%)	6/97 (6.19%)	0/65 (0.00%)	1/143 (0.70%)
# events	1	0	2	2	3	6	0	2

GASTROOESOPHAGEAL REFLUX DISEASE † 1								
# participants affected / at risk	1/15 (6.67%)	1/34 (2.94%)	2/48 (4.17%)	0/49 (0.00%)	1/49 (2.04%)	4/97 (4.12%)	1/65 (1.54%)	5/143 (3.50%)
# events	1	1	2	0	1	4	1	5
IRRITABLE BOWEL SYNDROME † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	1/97 (1.03%)	0/65 (0.00%)	0/143 (0.00%)
# events	1	0	0	0	0	1	0	0
MOUTH ULCERATION † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	1/97 (1.03%)	0/65 (0.00%)	0/143 (0.00%)
# events	1	0	0	0	0	1	0	0
NAUSEA † 1								
# participants affected / at risk	6/15 (40.00%)	9/34 (26.47%)	15/48 (31.25%)	13/49 (26.53%)	22/49 (44.90%)	32/97 (32.99%)	23/65 (35.38%)	22/143 (15.38%)
# events	7	12	17	14	31	41	23	30
ORAL MUCOSAL BLISTERING † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	1	0	0	0	0	0	0	0
TOOTHACHE † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	1/48 (2.08%)	1/49 (2.04%)	0/49 (0.00%)	1/97 (1.03%)	1/65 (1.54%)	4/143 (2.80%)
# events	1	0	1	1	0	1	1	4
VOMITING † 1								
# participants affected / at risk	2/15 (13.33%)	4/34 (11.76%)	7/48 (14.58%)	5/49 (10.20%)	10/49 (20.41%)	11/97 (11.34%)	6/65 (9.23%)	9/143 (6.29%)
# events	3	4	10	5	15	12	6	14
General disorders								
ASTHENIA † 1								
# participants affected / at risk	1/15 (6.67%)	9/34 (26.47%)	8/48 (16.67%)	7/49 (14.29%)	10/49 (20.41%)	20/97 (20.62%)	4/65 (6.15%)	7/143 (4.90%)
# events	1	9	9	12	15	31	4	7
CHEST PAIN † 1								
# participants affected / at risk	1/15 (6.67%)	1/34 (2.94%)	1/48 (2.08%)	2/49 (4.08%)	1/49 (2.04%)	2/97 (2.06%)	1/65 (1.54%)	3/143 (2.10%)
# events	1	1	1	3	1	2	1	3
CHILLS † 1								
# participants affected / at risk	4/15 (26.67%)	11/34 (32.35%)	19/48 (39.58%)	20/49 (40.82%)	19/49 (38.78%)	28/97 (28.87%)	27/65 (41.54%)	3/143 (2.10%)
# events	5	16	20	22	24	33	33	3
FATIGUE † 1								
# participants affected / at risk	10/15 (66.67%)	14/34 (41.18%)	25/48 (52.08%)	31/49 (63.27%)	24/49 (48.98%)	45/97 (46.39%)	40/65 (61.54%)	38/143 (26.57%)
# events	12	16	31	39	33	58	48	43
FEELING HOT † 1								
# participants affected / at risk	1/15 (6.67%)	1/34 (2.94%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	1	1	0	0	0	0	0	0
INFLUENZA LIKE ILLNESS † 1								
# participants affected / at risk	5/15 (33.33%)	6/34 (17.65%)	7/48 (14.58%)	12/49 (24.49%)	10/49 (20.41%)	21/97 (21.65%)	15/65 (23.08%)	0/143 (0.00%)

# events	5	6	8	13	13	24	15	0
INJECTION SITE ERYTHEMA † 1								
# participants affected / at risk	4/15 (26.67%)	4/34 (11.76%)	10/48 (20.83%)	10/49 (20.41%)	11/49 (22.45%)	15/97 (15.46%)	10/65 (15.38%)	1/143 (0.70%)
# events	4	4	11	10	11	17	10	1
INJECTION SITE RASH † 1								
# participants affected / at risk	1/15 (6.67%)	2/34 (5.88%)	1/48 (2.08%)	1/49 (2.04%)	0/49 (0.00%)	0/97 (0.00%)	1/65 (1.54%)	0/143 (0.00%)
# events	1	2	1	1	0	0	1	0
INJECTION SITE REACTION † 1								
# participants affected / at risk	2/15 (13.33%)	6/34 (17.65%)	9/48 (18.75%)	5/49 (10.20%)	5/49 (10.20%)	9/97 (9.28%)	7/65 (10.77%)	0/143 (0.00%)
# events	2	6	9	5	5	9	7	0
IRRITABILITY † 1								
# participants affected / at risk	3/15 (20.00%)	9/34 (26.47%)	7/48 (14.58%)	4/49 (8.16%)	9/49 (18.37%)	12/97 (12.37%)	7/65 (10.77%)	7/143 (4.90%)
# events	3	9	7	8	10	14	8	7
MALAISE † 1								
# participants affected / at risk	1/15 (6.67%)	1/34 (2.94%)	1/48 (2.08%)	1/49 (2.04%)	0/49 (0.00%)	2/97 (2.06%)	0/65 (0.00%)	1/143 (0.70%)
# events	1	3	1	1	0	2	0	1
PAIN † 1								
# participants affected / at risk	1/15 (6.67%)	4/34 (11.76%)	4/48 (8.33%)	3/49 (6.12%)	3/49 (6.12%)	8/97 (8.25%)	3/65 (4.62%)	1/143 (0.70%)
# events	1	6	5	3	4	8	3	1
PYREXIA † 1								
# participants affected / at risk	4/15 (26.67%)	13/34 (38.24%)	19/48 (39.58%)	17/49 (34.69%)	20/49 (40.82%)	30/97 (30.93%)	23/65 (35.38%)	6/143 (4.20%)
# events	4	15	26	22	26	39	27	6
Hepatobiliary disorders								
HEPATOMEGALY † 1								
# participants affected / at risk	1/15 (6.67%)	2/34 (5.88%)	4/48 (8.33%)	3/49 (6.12%)	5/49 (10.20%)	9/97 (9.28%)	4/65 (6.15%)	1/143 (0.70%)
# events	1	2	4	3	5	10	4	1
Immune system disorders								
SEASONAL ALLERGY † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	1/48 (2.08%)	1/49 (2.04%)	3/49 (6.12%)	0/97 (0.00%)	0/65 (0.00%)	2/143 (1.40%)
# events	0	0	1	1	3	0	0	2
Infections and infestations								
BRONCHITIS † 1								
# participants affected / at risk	0/15 (0.00%)	2/34 (5.88%)	1/48 (2.08%)	3/49 (6.12%)	1/49 (2.04%)	4/97 (4.12%)	0/65 (0.00%)	5/143 (3.50%)
# events	0	2	1	3	1	4	0	5
FOLLICULITIS † 1								
# participants affected / at risk	0/15 (0.00%)	2/34 (5.88%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	2/97 (2.06%)	0/65 (0.00%)	0/143 (0.00%)
# events	0	3	0	0	0	2	0	0
INFLUENZA † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	3/48 (6.25%)	4/49 (8.16%)	3/49 (6.12%)	4/97 (4.12%)	0/65 (0.00%)	1/143 (0.70%)
# events	0	0	5	4	3	4	0	1
LOWER RESPIRATORY TRACT INFECTION † 1								

# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	1/48 (2.08%)	0/49 (0.00%)	0/49 (0.00%)	1/97 (1.03%)	0/65 (0.00%)	0/143 (0.00%)
# events	1	0	1	0	0	1	0	0
NASOPHARYNGITIS † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	3/48 (6.25%)	1/49 (2.04%)	1/49 (2.04%)	4/97 (4.12%)	0/65 (0.00%)	2/143 (1.40%)
# events	0	0	4	1	2	6	0	2
ORAL HERPES † 1								
# participants affected / at risk	1/15 (6.67%)	4/34 (11.76%)	1/48 (2.08%)	1/49 (2.04%)	1/49 (2.04%)	7/97 (7.22%)	1/65 (1.54%)	3/143 (2.10%)
# events	1	4	1	2	1	7	1	3
PHARYNGITIS STREPTOCOCCAL † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	2/48 (4.17%)	1/49 (2.04%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	2	0	2	1	0	0	0	0
SINUSITIS † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	5/48 (10.42%)	1/49 (2.04%)	1/49 (2.04%)	3/97 (3.09%)	0/65 (0.00%)	2/143 (1.40%)
# events	3	0	6	1	1	3	0	2
UPPER RESPIRATORY TRACT INFECTION † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	3/48 (6.25%)	1/49 (2.04%)	2/49 (4.08%)	6/97 (6.19%)	0/65 (0.00%)	1/143 (0.70%)
# events	0	0	3	1	2	7	0	1
URINARY TRACT INFECTION † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	1/49 (2.04%)	4/49 (8.16%)	1/97 (1.03%)	2/65 (3.08%)	2/143 (1.40%)
# events	0	0	0	1	4	1	2	5
VIRAL PHARYNGITIS † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	1	0	0	0	0	0	0	0
Injury, poisoning and procedural complications								
CONTUSION † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	1/48 (2.08%)	1/49 (2.04%)	3/49 (6.12%)	2/97 (2.06%)	0/65 (0.00%)	5/143 (3.50%)
# events	0	0	1	1	4	2	0	5
LIMB INJURY † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	0/48 (0.00%)	1/49 (2.04%)	3/49 (6.12%)	2/97 (2.06%)	0/65 (0.00%)	0/143 (0.00%)
# events	0	0	0	1	3	2	0	0
SUNBURN † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	0/48 (0.00%)	1/49 (2.04%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	1/143 (0.70%)
# events	1	0	0	1	0	0	0	1
Investigations								
HAEMOGLOBIN DECREASED † 1								
# participants affected / at risk	0/15 (0.00%)	1/34 (2.94%)	0/48 (0.00%)	0/49 (0.00%)	4/49 (8.16%)	0/97 (0.00%)	0/65 (0.00%)	9/143 (6.29%)
# events	0	1	0	0	4	0	0	10
WEIGHT DECREASED † 1								
# participants affected / at risk	0/15 (0.00%)	2/34 (5.88%)	1/48 (2.08%)	2/49 (4.08%)	2/49 (4.08%)	3/97 (3.09%)	3/65 (4.62%)	6/143 (4.20%)
# events	0	2	1	2	2	3	3	7
Metabolism and nutrition disorders								

ANOREXIA [† 1]								
# participants affected / at risk	**1/15 (6.67%)**	**3/34 (8.82%)**	**6/48 (12.50%)**	**6/49 (12.24%)**	**3/49 (6.12%)**	**4/97 (4.12%)**	**4/65 (6.15%)**	**5/143 (3.50%)**
# events	**1**	**3**	**6**	**7**	**3**	**4**	**4**	**5**
DECREASED APPETITE [† 1]								
# participants affected / at risk	**1/15 (6.67%)**	**3/34 (8.82%)**	**1/48 (2.08%)**	**4/49 (8.16%)**	**4/49 (8.16%)**	**5/97 (5.15%)**	**6/65 (9.23%)**	**8/143 (5.59%)**
# events	**1**	**3**	**1**	**4**	**5**	**5**	**6**	**8**
HYPERINSULINISM [† 1]								
# participants affected / at risk	**1/15 (6.67%)**	**0/34 (0.00%)**	**0/48 (0.00%)**	**0/49 (0.00%)**	**0/49 (0.00%)**	**0/97 (0.00%)**	**0/65 (0.00%)**	**0/143 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
HYPERTRIGLYCERIDAEMIA [† 1]								
# participants affected / at risk	**1/15 (6.67%)**	**0/34 (0.00%)**	**1/48 (2.08%)**	**1/49 (2.04%)**	**0/49 (0.00%)**	**2/97 (2.06%)**	**1/65 (1.54%)**	**1/143 (0.70%)**
# events	**1**	**0**	**2**	**1**	**0**	**2**	**1**	**1**
Musculoskeletal and connective tissue disorders								
ARTHRALGIA [† 1]								
# participants affected / at risk	**5/15 (33.33%)**	**5/34 (14.71%)**	**17/48 (35.42%)**	**15/49 (30.61%)**	**17/49 (34.69%)**	**35/97 (36.08%)**	**15/65 (23.08%)**	**8/143 (5.59%)**
# events	**6**	**10**	**28**	**24**	**18**	**46**	**22**	**8**
BACK PAIN [† 1]								
# participants affected / at risk	**3/15 (20.00%)**	**3/34 (8.82%)**	**4/48 (8.33%)**	**6/49 (12.24%)**	**5/49 (10.20%)**	**21/97 (21.65%)**	**10/65 (15.38%)**	**9/143 (6.29%)**
# events	**4**	**3**	**4**	**6**	**5**	**21**	**10**	**9**
BONE PAIN [† 1]								
# participants affected / at risk	**0/15 (0.00%)**	**2/34 (5.88%)**	**1/48 (2.08%)**	**0/49 (0.00%)**	**1/49 (2.04%)**	**3/97 (3.09%)**	**0/65 (0.00%)**	**1/143 (0.70%)**
# events	**0**	**2**	**1**	**0**	**1**	**3**	**0**	**1**
MUSCLE SPASMS [† 1]								
# participants affected / at risk	**0/15 (0.00%)**	**1/34 (2.94%)**	**4/48 (8.33%)**	**1/49 (2.04%)**	**3/49 (6.12%)**	**3/97 (3.09%)**	**1/65 (1.54%)**	**6/143 (4.20%)**
# events	**0**	**1**	**5**	**2**	**3**	**3**	**2**	**6**
MUSCULOSKELETAL STIFFNESS [† 1]								
# participants affected / at risk	**1/15 (6.67%)**	**0/34 (0.00%)**	**1/48 (2.08%)**	**1/49 (2.04%)**	**0/49 (0.00%)**	**1/97 (1.03%)**	**0/65 (0.00%)**	**2/143 (1.40%)**
# events	**1**	**0**	**1**	**1**	**0**	**1**	**0**	**2**
MYALGIA [† 1]								
# participants affected / at risk	**6/15 (40.00%)**	**8/34 (23.53%)**	**23/48 (47.92%)**	**16/49 (32.65%)**	**16/49 (32.65%)**	**37/97 (38.14%)**	**26/65 (40.00%)**	**6/143 (4.20%)**
# events	**7**	**10**	**28**	**20**	**20**	**39**	**32**	**7**
PAIN IN EXTREMITY [† 1]								
# participants affected / at risk	**2/15 (13.33%)**	**0/34 (0.00%)**	**1/48 (2.08%)**	**2/49 (4.08%)**	**1/49 (2.04%)**	**5/97 (5.15%)**	**1/65 (1.54%)**	**5/143 (3.50%)**
# events	**2**	**0**	**1**	**3**	**1**	**6**	**1**	**6**
Nervous system disorders								
APHASIA [† 1]								
# participants affected / at risk	**1/15 (6.67%)**	**0/34 (0.00%)**	**0/48 (0.00%)**	**0/49 (0.00%)**	**0/49 (0.00%)**	**0/97 (0.00%)**	**0/65 (0.00%)**	**0/143 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
BALANCE DISORDER [† 1]								
# participants affected / at risk	**1/15 (6.67%)**	**1/34 (2.94%)**	**1/48 (2.08%)**	**1/49 (2.04%)**	**0/49 (0.00%)**	**1/97 (1.03%)**	**0/65 (0.00%)**	**1/143 (0.70%)**
# events	**1**	**1**	**1**	**1**	**0**	**1**	**0**	**1**
DISTURBANCE IN								

ATTENTION † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	5/48 (10.42%)	5/49 (10.20%)	2/49 (4.08%)	4/97 (4.12%)	4/65 (6.15%)	5/143 (3.50%)
# events	0	0	6	5	2	5	4	5
DIZZINESS † 1								
# participants affected / at risk	2/15 (13.33%)	10/34 (29.41%)	10/48 (20.83%)	5/49 (10.20%)	4/49 (8.16%)	7/97 (7.22%)	6/65 (9.23%)	18/143 (12.59%)
# events	2	10	13	5	4	9	7	23
DYSGEUSIA † 1								
# participants affected / at risk	3/15 (20.00%)	4/34 (11.76%)	3/48 (6.25%)	2/49 (4.08%)	13/49 (26.53%)	23/97 (23.71%)	31/65 (47.69%)	14/143 (9.79%)
# events	3	4	4	2	16	26	33	14
HEADACHE † 1								
# participants affected / at risk	7/15 (46.67%)	20/34 (58.82%)	30/48 (62.50%)	28/49 (57.14%)	25/49 (51.02%)	52/97 (53.61%)	33/65 (50.77%)	11/143 (7.69%)
# events	9	24	39	47	37	65	43	16
HYPOAESTHESIA † 1								
# participants affected / at risk	0/15 (0.00%)	2/34 (5.88%)	0/48 (0.00%)	1/49 (2.04%)	3/49 (6.12%)	1/97 (1.03%)	2/65 (3.08%)	3/143 (2.10%)
# events	0	2	0	1	5	1	2	3
HYPOKINESIA † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	1	0	0	0	0	0	0	0
LETHARGY † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	1/48 (2.08%)	0/49 (0.00%)	1/49 (2.04%)	0/97 (0.00%)	1/65 (1.54%)	0/143 (0.00%)
# events	1	0	1	0	1	0	1	0
MEMORY IMPAIRMENT † 1								
# participants affected / at risk	0/15 (0.00%)	2/34 (5.88%)	3/48 (6.25%)	1/49 (2.04%)	3/49 (6.12%)	2/97 (2.06%)	3/65 (4.62%)	1/143 (0.70%)
# events	0	2	3	1	3	2	3	1
MIGRAINE † 1								
# participants affected / at risk	0/15 (0.00%)	2/34 (5.88%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	4/97 (4.12%)	2/65 (3.08%)	0/143 (0.00%)
# events	0	3	0	0	0	6	2	0
SPEECH DISORDER † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	1	0	0	0	0	0	0	0
TREMOR † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	2/48 (4.17%)	0/49 (0.00%)	3/49 (6.12%)	3/97 (3.09%)	2/65 (3.08%)	1/143 (0.70%)
# events	0	0	2	0	3	4	2	1
Psychiatric disorders								
ANXIETY † 1								
# participants affected / at risk	1/15 (6.67%)	4/34 (11.76%)	6/48 (12.50%)	4/49 (8.16%)	5/49 (10.20%)	8/97 (8.25%)	2/65 (3.08%)	6/143 (4.20%)
# events	3	4	7	4	5	10	2	6
CONFUSIONAL STATE † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	1/49 (2.04%)	0/97 (0.00%)	2/65 (3.08%)	1/143 (0.70%)
# events	1	0	0	0	1	0	2	1
DEPRESSION † 1								
# participants affected / at risk	4/15 (26.67%)	4/34 (11.76%)	12/48 (25.00%)	8/49 (16.33%)	16/49 (32.65%)	18/97 (18.56%)	5/65 (7.69%)	22/143 (15.38%)

# events	5	5	13	9	16	19	7	26
INITIAL INSOMNIA † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	0/48 (0.00%)	0/49 (0.00%)	1/49 (2.04%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	2	0	0	0	1	0	0	0
INSOMNIA † 1								
# participants affected / at risk	4/15 (26.67%)	9/34 (26.47%)	12/48 (25.00%)	11/49 (22.45%)	15/49 (30.61%)	20/97 (20.62%)	10/65 (15.38%)	23/143 (16.08%)
# events	4	12	14	13	18	23	10	23
MOOD SWINGS † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	1/48 (2.08%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	0/143 (0.00%)
# events	1	0	1	0	0	0	0	0
NERVOUSNESS † 1								
# participants affected / at risk	1/15 (6.67%)	3/34 (8.82%)	2/48 (4.17%)	0/49 (0.00%)	1/49 (2.04%)	3/97 (3.09%)	0/65 (0.00%)	1/143 (0.70%)
# events	1	3	4	0	1	3	0	1
SLEEP DISORDER † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	1/48 (2.08%)	2/49 (4.08%)	1/49 (2.04%)	2/97 (2.06%)	2/65 (3.08%)	1/143 (0.70%)
# events	1	0	1	3	1	2	2	1
Reproductive system and breast disorders								
SEXUAL DYSFUNCTION † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	1/48 (2.08%)	0/49 (0.00%)	0/49 (0.00%)	0/97 (0.00%)	0/65 (0.00%)	1/143 (0.70%)
# events	1	0	1	0	0	0	0	1
Respiratory, thoracic and mediastinal disorders								
COUGH † 1								
# participants affected / at risk	4/15 (26.67%)	7/34 (20.59%)	9/48 (18.75%)	5/49 (10.20%)	7/49 (14.29%)	10/97 (10.31%)	6/65 (9.23%)	17/143 (11.89%)
# events	4	12	9	5	8	12	7	20
DYSPNOEA † 1								
# participants affected / at risk	4/15 (26.67%)	4/34 (11.76%)	6/48 (12.50%)	6/49 (12.24%)	11/49 (22.45%)	11/97 (11.34%)	0/65 (0.00%)	19/143 (13.29%)
# events	4	5	9	6	14	11	0	21
DYSPNOEA EXERTIONAL † 1								
# participants affected / at risk	0/15 (0.00%)	1/34 (2.94%)	2/48 (4.17%)	0/49 (0.00%)	5/49 (10.20%)	1/97 (1.03%)	0/65 (0.00%)	11/143 (7.69%)
# events	0	1	3	0	5	1	0	11
EPISTAXIS † 1								
# participants affected / at risk	1/15 (6.67%)	2/34 (5.88%)	3/48 (6.25%)	2/49 (4.08%)	3/49 (6.12%)	2/97 (2.06%)	0/65 (0.00%)	3/143 (2.10%)
# events	4	3	3	2	4	12	0	26
INCREASED UPPER AIRWAY SECRETION † 1								
# participants affected / at risk	0/15 (0.00%)	2/34 (5.88%)	1/48 (2.08%)	1/49 (2.04%)	1/49 (2.04%)	3/97 (3.09%)	1/65 (1.54%)	3/143 (2.10%)
# events	0	2	1	1	1	3	1	3
NASAL CONGESTION † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	3/48 (6.25%)	1/49 (2.04%)	3/49 (6.12%)	1/97 (1.03%)	2/65 (3.08%)	2/143 (1.40%)
# events	1	0	3	1	4	1	2	3
NASAL DRYNESS † 1								
# participants affected /	1/15 (6.67%)	0/34 (0.00%)	1/48 (2.08%)	0/49 (0.00%)	0/49 (0.00%)	1/97 (1.03%)	0/65 (0.00%)	0/143 (0.00%)

at risk								
# events	1	0	1	0	0	1	0	0
PHARYNGOLARYNGEAL PAIN † 1								
# participants affected / at risk	2/15 (13.33%)	0/34 (0.00%)	5/48 (10.42%)	2/49 (4.08%)	5/49 (10.20%)	7/97 (7.22%)	3/65 (4.62%)	7/143 (4.90%)
# events	2	0	6	3	6	7	3	7
PRODUCTIVE COUGH † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	2/48 (4.17%)	1/49 (2.04%)	0/49 (0.00%)	2/97 (2.06%)	0/65 (0.00%)	0/143 (0.00%)
# events	1	0	2	1	0	2	0	0
RHINORRHOEA † 1								
# participants affected / at risk	1/15 (6.67%)	1/34 (2.94%)	0/48 (0.00%)	2/49 (4.08%)	2/49 (4.08%)	3/97 (3.09%)	1/65 (1.54%)	0/143 (0.00%)
# events	1	2	0	2	2	3	1	0
SINUS CONGESTION † 1								
# participants affected / at risk	1/15 (6.67%)	1/34 (2.94%)	4/48 (8.33%)	0/49 (0.00%)	0/49 (0.00%)	4/97 (4.12%)	1/65 (1.54%)	1/143 (0.70%)
# events	1	2	4	0	0	4	1	1
Skin and subcutaneous tissue disorders								
ALOPECIA † 1								
# participants affected / at risk	0/15 (0.00%)	5/34 (14.71%)	10/48 (20.83%)	4/49 (8.16%)	17/49 (34.69%)	21/97 (21.65%)	2/65 (3.08%)	19/143 (13.29%)
# events	0	6	10	5	18	21	2	19
DERMATITIS † 1								
# participants affected / at risk	0/15 (0.00%)	0/34 (0.00%)	1/48 (2.08%)	0/49 (0.00%)	0/49 (0.00%)	6/97 (6.19%)	0/65 (0.00%)	2/143 (1.40%)
# events	0	0	1	0	0	6	0	2
DRY SKIN † 1								
# participants affected / at risk	1/15 (6.67%)	9/34 (26.47%)	6/48 (12.50%)	5/49 (10.20%)	8/49 (16.33%)	10/97 (10.31%)	2/65 (3.08%)	3/143 (2.10%)
# events	1	9	7	5	8	10	2	4
ERYTHEMA † 1								
# participants affected / at risk	0/15 (0.00%)	2/34 (5.88%)	2/48 (4.17%)	0/49 (0.00%)	0/49 (0.00%)	2/97 (2.06%)	0/65 (0.00%)	0/143 (0.00%)
# events	0	2	2	0	0	2	0	0
HYPERHIDROSIS † 1								
# participants affected / at risk	0/15 (0.00%)	3/34 (8.82%)	2/48 (4.17%)	3/49 (6.12%)	3/49 (6.12%)	4/97 (4.12%)	4/65 (6.15%)	0/143 (0.00%)
# events	0	4	3	3	3	5	4	0
NIGHT SWEATS † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	2/48 (4.17%)	0/49 (0.00%)	1/49 (2.04%)	4/97 (4.12%)	1/65 (1.54%)	0/143 (0.00%)
# events	1	0	2	0	1	4	1	0
PALMAR ERYTHEMA † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	1/48 (2.08%)	2/49 (4.08%)	1/49 (2.04%)	0/97 (0.00%)	1/65 (1.54%)	2/143 (1.40%)
# events	1	0	1	2	1	0	1	2
PHOTOSENSITIVITY REACTION † 1								
# participants affected / at risk	1/15 (6.67%)	0/34 (0.00%)	2/48 (4.17%)	1/49 (2.04%)	0/49 (0.00%)	2/97 (2.06%)	1/65 (1.54%)	0/143 (0.00%)
# events	1	0	3	1	0	2	1	0
PRURITUS † 1								
# participants affected / at risk	1/15 (6.67%)	9/34 (26.47%)	8/48 (16.67%)	4/49 (8.16%)	5/49 (10.20%)	9/97 (9.28%)	2/65 (3.08%)	15/143 (10.49%)
# events	1	12	10	4	5	9	2	15
† 1								

RASH								
# participants affected / at risk	**2/15 (13.33%)**	**4/34 (11.76%)**	**5/48 (10.42%)**	**3/49 (6.12%)**	**8/49 (16.33%)**	**9/97 (9.28%)**	**2/65 (3.08%)**	**9/143 (6.29%)**
# events	**3**	**4**	**5**	**3**	**12**	**10**	**2**	**10**
SPIDER NAEVUS † 1								
# participants affected / at risk	**1/15 (6.67%)**	**0/34 (0.00%)**	**1/48 (2.08%)**	**0/49 (0.00%)**	**0/49 (0.00%)**	**0/97 (0.00%)**	**1/65 (1.54%)**	**0/143 (0.00%)**
# events	**1**	**0**	**1**	**0**	**0**	**0**	**1**	**0**
SWELLING FACE † 1								
# participants affected / at risk	**1/15 (6.67%)**	**0/34 (0.00%)**	**0/48 (0.00%)**	**0/49 (0.00%)**	**0/49 (0.00%)**	**1/97 (1.03%)**	**0/65 (0.00%)**	**1/143 (0.70%)**
# events	**1**	**0**	**0**	**0**	**0**	**1**	**0**	**1**
Surgical and medical procedures								
CYST DRAINAGE † 1								
# participants affected / at risk	**1/15 (6.67%)**	**0/34 (0.00%)**	**0/48 (0.00%)**	**0/49 (0.00%)**	**0/49 (0.00%)**	**0/97 (0.00%)**	**0/65 (0.00%)**	**0/143 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Vascular disorders								
HYPERTENSION † 1								
# participants affected / at risk	**2/15 (13.33%)**	**1/34 (2.94%)**	**2/48 (4.17%)**	**4/49 (8.16%)**	**2/49 (4.08%)**	**4/97 (4.12%)**	**0/65 (0.00%)**	**1/143 (0.70%)**
# events	**3**	**1**	**2**	**4**	**2**	**4**	**0**	**1**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 10.0

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

The implementation of amendment 2 led to changes in boceprevir dose in all treatment arms and different overall lengths of therapy within the same treatment arm, making the SVR endpoint uninterpretable.

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:** The principal investigator (PI) agrees to provide review copies to the sponsor 30 days prior to submission. The sponsor shall have editorial rights and the right to review and comment on the data analysis and presentation with regard to proprietary information, accuracy of information, and to ensure that the presentation is fairly balanced and in compliance with regulations. If the parties disagree, the PI agrees to meet with the sponsor to discuss and resolve any such issues or disagreement.

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Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00160251 History of Changes
Other Study ID Numbers:	P03659
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Health Authority:	United States: Food and Drug Administration

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