ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"
Search for studies:
Search

Advanced Search | Help | Studies by Topic | Glossary

Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

Home > Find Studies > Search Results > Study Record Detail
Text Size

Trial record **1 of 1** for: NCT00959699
Previous Study | Return to List | Next Study

A Phase 2b, Safety and Efficacy Study of Boceprevir in Patients Coinfected With HIV and Hepatitis C (P05411 AM4)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00959699

First received: July 29, 2009
Last updated: September 4, 2015
Last verified: September 2015
History of Changes

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

Purpose

The primary objective of this trial is to compare the efficacy of boceprevir (SCH 503034) 800 mg three times a day (TID) orally (PO) in combination with peginterferon alfa-2b (PegIFN-2b) 1.5 µg/kg weekly (QW) subcutaneously (SC) plus weight-based dosing (WBD) of ribavirin (RBV) (600 mg/day to 1400 mg/day) PO to therapy with PegIFN-2b + RBV alone in adult participants coinfected with human immunodeficiency virus (HIV) and previously untreated chronic hepatitis C virus (HCV) genotype 1.

Boceprevir is a potent, orally administered, novel serine protease inhibitor, specifically designed to inhibit the HCV nonstructural protein 3 (NS3) protease and, thereby, inhibit viral replication in HCV-infected host cells. The mechanism of inhibition represents a new mechanism of action compared to both interferon alfa and ribavirin. Based on previous experience with PegIFN-2b and RBV in combination with boceprevir in the HCV-monoinfected population, this combination treatment is expected to provide significant benefit to the HIV/HCV coinfected population. Given the high unmet medical need of these participants and the benefit of the addition of boceprevir to PegIFN-2b/RBV, it is important to demonstrate the safety and efficacy of boceprevir in combination with PegIFN-2b/RBV in participants coinfected with HIV/HCV.

This is a randomized, multi-center trial, double-blinded for boceprevir or placebo in combination with open-label PegIFN-2b/RBV in participants coinfected with HIV and previously untreated chronic HCV (genotype 1), to be conducted in conformance with Good Clinical Practice (GCP). This trial consists of two arms, one control arm (Arm 1) and one experimental arm (Arm 2). Participants in the control arm (Arm 1) may receive boceprevir/PegIFN-2b/RBV via a crossover arm.

Condition	Intervention	Phase
HIV Infections Hepatitis C HCV Infection	Drug: PegIFN-2b Drug: RBV Drug: Placebo to Boceprevir Drug: Boceprevir	Phase 2

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

Official Title: A Phase 2b, Safety and Efficacy Study of Boceprevir in Patients Coinfected With HIV and Hepatitis C (Protocol No. P05411)

Resource links provided by NLM:

MedlinePlus related topics: HIV/AIDS Hepatitis Hepatitis A Hepatitis C

Drug Information available for: Peginterferon Alfa-2b Boceprevir

U.S. FDA Resources

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

Primary Outcome Measures:

- Percentage of Participants Achieving Sustained Viral Response (SVR) at Follow-up Week 24 (FW24) Among Randomized Participants Who Received At Least One Dose of Trial Medication [Time Frame: Up to Week 72] [Designated as safety issue: No]

  SVR24 is defined as undetectable plasma hepatitis C virus ribonucleic acid (HCV-RNA) at 24 weeks after the end of all study treatment. If there was no value in the FW24 visit window, the closest value available chronologically after this window was used; if a value was still missing after that, the value from Follow-up Week 12 (FW12) was used. HCV-RNA is detected by a nucleic acid amplification test and the lower limit of detection for this assay is 9.3 IU/mL.

Secondary Outcome Measures:

- Percentage of Participants Achieving SVR24 Among Randomized Participants Who Received At Least One Dose of Boceprevir (Experimental) or Placebo (Control) [Time Frame: Up to Week 72] [Designated as safety issue: No]

  SVR24 is defined as undetectable plasma HCV-RNA 24 weeks after the end of all study treatment. If there was no value in the FW24 visit window, the closest value available chronologically after this window was used; if a value was still missing after that, the value from FW12 was used. HCV-RNA is detected by a nucleic acid amplification test and the lower limit of detection for this assay is 9.3 IU/mL.

- Percentage of Participants With Early Virologic Response (EVR) Who Achieved SVR24 [Time Frame: Up to Week 12] [Designated as safety issue: No]

  EVR was defined as undetectable HCV-RNA at Treatment Week (TW) 2, 4, 8, or 12. HCV-RNA was detected by a nucleic acid amplification test and the lower limit of detection for this assay is 9.3 IU/mL.

- Percentage of Participants With Undetectable HCV-RNA at Follow-up Week 12 (FW12) [Time Frame: Up to Week 60] [Designated as safety issue: No]

  The virologic response at FW12 was considered SVR12 with an additional rule for handling missing data: participants with missing HCV-RNA assessment at FW12 but having non-missing, undetectable HCV-RNA assessments at both FW4 and FW24, were assumed to be responders for SVR12. HCV-RNA was detected by a nucleic acid amplification test and the lower limit of detection for this assay is 9.3 IU/mL.

- Change From Baseline in log10 HCV-RNA at Treatment Week 4 (TW4) [Time Frame: Baseline and Week 4] [Designated as safety issue: No]

  This is a measure of the change in the amount of HCV-RNA in the plasma at the end of 4 weeks of treatment. HCV-RNA was detected by a nucleic acid amplification test and the lower limit of detection for this assay is 9.3 IU/mL.

- Percentage of Participants With HCV Virologic Breakthrough or Incomplete Virologic Response/Rebound [Time Frame: Up to Week 72] [Designated as safety issue: No]

  Virologic breakthrough is defined as achieving undetectable HCV-RNA and subsequently having an HCV-RNA level of >1000 IU/mL. Incomplete Virologic Response/Rebound is defined as having a one log10 increase in HCV-RNA from the participant's nadir, with an HCV-RNA >1000 IU/mL. HCV-RNA was detected by a nucleic acid amplification test and the lower limit of detection for this assay is 9.3 IU/mL.

Enrollment:	99
Study Start Date:	November 2009
Study Completion Date:	October 2012
Primary Completion Date:	May 2012 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions

Placebo Comparator: PegIFN-2b + RBV PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600-1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by placebo to boceprevir plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up (Control Arm). Participants who do not achieve HCV-RNA <9.3 IU/mL by Treatment Week 24 (TW24) are eligible to cross-over and receive boceprevir along with the PegIFN-2b and RBV for up to 44 weeks.	Drug: PegIFN-2b PegIFN-2b (1.5 µg/kg/week subcutaneously) Other Names: • SCH 054031 • MK-4031 • Pegylated interferon alfa-2b • Peginterferon alfa-2b Drug: RBV Ribavirin (600-1400 mg/day, orally, divided into two daily doses) Other Name: Ribavirin Drug: Placebo to Boceprevir Placebo to boceprevir (orally, three times per day)
Active Comparator: PegIFN-2b + RBV + Boceprevir PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600- 1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by boceprevir (800 mg, orally, 3 times per day) plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up.	Drug: PegIFN-2b PegIFN-2b (1.5 µg/kg/week subcutaneously) Other Names: • SCH 054031 • MK-4031 • Pegylated interferon alfa-2b • Peginterferon alfa-2b Drug: RBV Ribavirin (600-1400 mg/day, orally, divided into two daily doses) Other Name: Ribavirin Drug: Boceprevir Boceprevir (800 mg, orally, three times per day) Other Names: • SCH 503034 • MK-3034 • Victrelis

Eligibility

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

Criteria

Inclusion Criteria:

- >=18 and <=65 years of age
- Body weight >=40 and <=125 kg
- Documented history of HIV infection for greater than 6 months prior to Day 1
- On an optimized anti-retroviral treatment regimen (OTR) with stable HIV disease with CD4 >=200 cells/µL and HIV-1 RNA viral load <50 copies/mL
- Documented chronic hepatitis C (CHC) genotype 1 infection (greater than 6 months prior to Day 1)
- Use of acceptable methods of contraception 2 weeks prior to Day 1 and at least 6 months or longer after treatment
- Liver biopsy with histology consistent with CHC and no other etiology

Exclusion Criteria:

- Participants who received prior treatment for hepatitis C other than herbal remedies except those with known hepatotoxicity
- Coinfected with hepatitis B virus (Hepatitis B surface antigen (HBsAg) positive) and/or demonstrating signs and symptoms consistent with concomitant infection
- Evidence of decompensated liver disease
- Participants who have changed their anti-retroviral regimen within the last 3 months prior to Day 1 or had first initiated anti-retroviral therapy within the last 6 months prior to Day 1
- Use of certain HIV medications will not be allowed. Medications will be reviewed by the Investigator
- History of clinically significant opportunistic infections (except oral thrush) within the last year prior to Day 1
- Current evidence of substance abuse within 3 years of the Screening Visit
- History of a clinical diagnosis within the past 6 months of substance abuse prior to Day 1
- Participants receiving opiate agonist substitution therapy but not enrolled in an opiate substitution maintenance program
- History of marijuana use deemed excessive by the Investigator
- Infected with HIV-2
- Use of any HIV protease inhibitor without the coadministration of ritonavir within one month of Day 1 and throughout the period of the trial
- Participants receiving any of the following medication(s) within 2 weeks prior to the Day 1 visit: alfuzosin, antiarrhythmics (amiodarone, bepridil, flecainide, propafenone, and quinidine), ergot derivatives, cisapride, lovastatin, simvastatin, pimozide, triazolam, and orally administered midazolam.

Key Laboratory Exclusion Criteria:

- Hematologic, biochemical, and serologic criteria (growth factors may not be used to achieve trial entry requirements):
  - Hemoglobin <11 g/dL for females and <12 g/dL for males
  - Neutrophils <1500/mm^3 (blacks/African-Americans: <1200/mm^3)
  - Platelets <100,000/mm^3
  - Direct bilirubin >1.5 x ULN (upper limit of normal) of the laboratory reference range. Total bilirubin >1.6 mg/dL unless history of Gilbert's disease or antiretroviral regimen contains atazanavir. If Gilbert's disease is the proposed etiology, this must be documented in the participant's chart
- Alpha fetoprotein (AFP):
  - AFP >100 ng/mL OR
  - AFP 50 to 100 ng/mL (requires a liver ultrasound and participants with findings suspicious for hepatocellular carcinoma are excluded)

Contacts and Locations

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

information, see Learn About Clinical Studies.

No Contacts or Locations Provided

More Information

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

Sulkowski M, Pol S, Mallolas J, Fainboim H, Cooper C, Slim J, Rivero A, Mak C, Thompson S, Howe AY, Wenning L, Sklar P, Wahl J, Greaves W; P05411 study investigators. Boceprevir versus placebo with pegylated interferon alfa-2b and ribavirin for treatment of hepatitis C virus genotype 1 in patients with HIV: a randomised, double-blind, controlled phase 2 trial. Lancet Infect Dis. 2013 Jul;13(7):597-605. doi: 10.1016/S1473-3099(13)70149-X. Epub 2013 Jun 12.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00959699 History of Changes
Other Study ID Numbers:	P05411 MK-3034-025
Study First Received:	July 29, 2009
Results First Received:	May 8, 2013
Last Updated:	September 4, 2015
Health Authority:	United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
coinfection
protease inhibitor
HIV

Additional relevant MeSH terms:

Communicable Diseases	Liver Diseases
Hepatitis	Picornaviridae Infections
Hepatitis A	RNA Virus Infections
Hepatitis C	Virus Diseases
Infection	Peginterferon alfa-2b
Digestive System Diseases	Anti-Infective Agents
Enterovirus Infections	Antiviral Agents
Flaviviridae Infections	Pharmacologic Actions
Hepatitis, Viral, Human	Therapeutic Uses

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

Copyright | Privacy | Accessibility | Viewers and Players | Freedom of Information Act | USA.gov
U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health and Human Services

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"
Search for studies:
Search

Advanced Search | Help | Studies by Topic | Glossary

Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

Home > Find Studies > Search Results > Study Record Detail
Text Size

Trial record **1 of 1** for: NCT00959699
Previous Study | Return to List | Next Study

A Phase 2b, Safety and Efficacy Study of Boceprevir in Patients Coinfected With HIV and Hepatitis C (P05411 AM4)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00959699

First received: July 29, 2009
Last updated: September 4, 2015
Last verified: September 2015
History of Changes

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

Results First Received: May 8, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Conditions:	HIV Infections Hepatitis C HCV Infection
Interventions:	Drug: PegIFN-2b Drug: RBV Drug: Placebo to Boceprevir Drug: Boceprevir

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

One participant in the pegylated interferon alfa-2b (PegIFN-2b) + ribavirin (RBV) + boceprevir group withdrew from the study after randomization but prior to administration of any study treatment.

Reporting Groups

	Description
PegIFN-2b + RBV	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600-1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by placebo to boceprevir plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up (Control Arm). Participants who do not achieve HCV-RNA <9.3 IU/mL by Treatment Week 24 (TW24) are eligible to cross-over and receive boceprevir along with the PegIFN-2b and RBV for up to 44 weeks.
PegIFN-2b + RBV + Boceprevir	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600- 1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by boceprevir (800 mg, orally, 3 times per day) plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up.

Participant Flow for 2 periods

Period 1: Treatment Period

	PegIFN-2b + RBV	PegIFN-2b + RBV + Boceprevir
STARTED	34	65
Treated	34	64
COMPLETED	11 [1]	40
NOT COMPLETED	23	25
Adverse Event	3	13
Lack of Efficacy	15	6
Lost to Follow-up	0	1
Withdrawal by Subject	1	3
Non-Compliance with Protocol	0	1
Did not receive treatment	0	1
Futility/crossover to boceprevir	4	0

[1] At TW24, 4 participants not achieving undetectable HCV-RNA crossed-over and received boceprevir.

Period 2: Follow-up Period

	PegIFN-2b + RBV	PegIFN-2b + RBV + Boceprevir
STARTED	33 [1]	62 [2]
COMPLETED	27	56
NOT COMPLETED	6	6
Lost to Follow-up	3	2
Withdrawal by Subject	3	4

[1] 1 participant didn't enter Follow-up; participants discontinuing treatment could enter Follow-up.
[2] 2 participants didn't enter Follow-up; participants discontinuing treatment could enter Follow-up.

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
PegIFN-2b + RBV	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600-1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by placebo to boceprevir plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up (Control Arm). Participants who do not achieve HCV-RNA <9.3 IU/mL by Treatment Week 24 (TW24) are eligible to cross-over and receive boceprevir along with the PegIFN-2b and RBV for up to 44 weeks.
PegIFN-2b + RBV + Boceprevir	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600- 1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by boceprevir (800 mg, orally, 3 times per day) plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up.
Total	Total of all reporting groups

Baseline Measures

	PegIFN-2b + RBV	**PegIFN-2b + RBV + Boceprevir**	**Total**
Number of Participants [units: participants]	**34**	**64**	**98**
Age [units: years] Mean (Standard Deviation)	**45.1 (9.8)**	**42.9 (8.3)**	**43.6 (8.8)**
Gender [units: participants]			
Female	**12**	**18**	**30**
Male	**22**	**46**	**68**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants Achieving Sustained Viral Response (SVR) at Follow-up Week 24 (FW24) Among Randomized Participants Who Received At Least One Dose of Trial Medication [Time Frame: Up to Week 72]

Measure Type	Primary
Measure Title	Percentage of Participants Achieving Sustained Viral Response (SVR) at Follow-up Week 24 (FW24) Among Randomized Participants Who Received At Least One Dose of Trial Medication
Measure Description	SVR24 is defined as undetectable plasma hepatitis C virus ribonucleic acid (HCV-RNA) at 24 weeks after the end of all study treatment. If there was no value in the FW24 visit window, the closest value available chronologically after this window was used; if a value was still missing after that, the value from Follow-up Week 12 (FW12) was used. HCV-RNA is detected by a nucleic acid amplification test and the lower limit of detection for this assay is 9.3 IU/mL.
Time Frame	Up to Week 72

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 randomized participants receiving at least one dose of any study medication (Full Analysis Set); this includes 3 participants who did not enter the Follow-Up Period.

Reporting Groups

	Description
PegIFN-2b + RBV	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600-1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by placebo to boceprevir plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up (Control Arm). Participants who do not achieve HCV-RNA <9.3 IU/mL by Treatment Week 24 (TW24) are eligible to cross-over and receive boceprevir along with the PegIFN-2b and RBV for up to 44 weeks.
PegIFN-2b + RBV + Boceprevir	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600- 1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by boceprevir (800 mg, orally, 3 times per day) plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up.

Measured Values

	PegIFN-2b + RBV	**PegIFN-2b + RBV + Boceprevir**
Number of Participants Analyzed [units: participants]	**34**	**64**
Percentage of Participants Achieving Sustained Viral Response (SVR) at Follow-up Week 24 (FW24) Among Randomized Participants Who Received At Least One Dose of Trial Medication [units: percentage of participants]	**29.4**	**62.5**

Statistical Analysis 1 for Percentage of Participants Achieving Sustained Viral Response (SVR) at Follow-up Week 24 (FW24) Among Randomized Participants Who Received At Least One Dose of Trial Medication

Groups [1]	All groups
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.0008
Strata-Adjusted Difference [4]	33.7
95% Confidence Interval	14.1 to 53.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The methodology for 95% Confidence Interval (CI) is based on a Modified Koch approach which adjusted for Randomization Strata of Cirrhosis/Fibrosis (Yes or No). The adjustment of randomization strata of HCV-RNA (< or >= 800,000 IU/mL) was not possible due to sparse data.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Cochran-Mantel-Haenszel p-value is adjusted for randomization strata of HCV-RNA (< or >= 800,000 IU/mL) and

	Cirrhosis/Fibrosis (Yes or No)
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Percentage of Participants Achieving SVR24 Among Randomized Participants Who Received At Least One Dose of Boceprevir (Experimental) or Placebo (Control) [Time Frame: Up to Week 72]

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving SVR24 Among Randomized Participants Who Received At Least One Dose of Boceprevir (Experimental) or Placebo (Control)
Measure Description	SVR24 is defined as undetectable plasma HCV-RNA 24 weeks after the end of all study treatment. If there was no value in the FW24 visit window, the closest value available chronologically after this window was used; if a value was still missing after that, the value from FW12 was used. HCV-RNA is detected by a nucleic acid amplification test and the lower limit of detection for this assay is 9.3 IU/mL.
Time Frame	Up to Week 72
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 randomized participants receiving one dose of boceprevir (PegIFN-2b + RBV + Boceprevir group) or placebo to boceprevir (PegIFN-2b + RBV group), defined as the Modified Intent-to-Treat Population; this includes 2 participants who did not enter the Follow-up Period.

Reporting Groups

	Description
PegIFN-2b + RBV	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600-1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by placebo to boceprevir plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up (Control Arm). Participants who do not achieve HCV-RNA <9.3 IU/mL by Treatment Week 24 (TW24) are eligible to cross-over and receive boceprevir along with the PegIFN-2b and RBV for up to 44 weeks.
PegIFN-2b + RBV + Boceprevir	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600- 1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by boceprevir (800 mg, orally, 3 times per day) plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up.

Measured Values

	PegIFN-2b + RBV	**PegIFN-2b + RBV + Boceprevir**
Number of Participants Analyzed [units: participants]	**33**	**62**
Percentage of Participants Achieving SVR24 Among Randomized Participants Who Received At Least One Dose of Boceprevir (Experimental) or Placebo (Control) [units: percentage of participants]	**30.3**	**64.5**

Statistical Analysis 1 for Percentage of Participants Achieving SVR24 Among Randomized Participants Who Received At Least One Dose of Boceprevir (Experimental) or Placebo (Control)

Groups [1]	All groups

Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.0007
Observed Difference [4]	34.2
95% Confidence Interval	14.5 to 53.9

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The methodology for 95% CI is based on the asymptotic normal approximation to the binomial distribution
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Cochran-Mantel-Haenszel p-value is adjusted for randomization strata of HCV-RNA (< or >= 800,000 IU/mL) and Cirrhosis/Fibrosis (Yes or No)
[4]	Other relevant estimation information:
	No text entered.

3. Secondary: Percentage of Participants With Early Virologic Response (EVR) Who Achieved SVR24 [Time Frame: Up to Week 12]

Measure Type	Secondary
Measure Title	Percentage of Participants With Early Virologic Response (EVR) Who Achieved SVR24
Measure Description	EVR was defined as undetectable HCV-RNA at Treatment Week (TW) 2, 4, 8, or 12. HCV-RNA was detected by a nucleic acid amplification test and the lower limit of detection for this assay is 9.3 IU/mL.
Time Frame	Up to Week 12
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 randomized participants receiving at least one dose of any study medication (Full Analysis Set); this includes 3 participants who did not enter the Follow-Up Period. No participants had undetectable HCV-RNA at Week 2; the “n” value in the table below represents the number of participants with EVR at that time point.

Reporting Groups

	Description
PegIFN-2b + RBV	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600-1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by placebo to boceprevir plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up (Control Arm). Participants who do not achieve HCV-RNA <9.3 IU/mL by Treatment Week 24 (TW24) are eligible to cross-over and receive boceprevir along with the PegIFN-2b and RBV for up to 44 weeks.
PegIFN-2b + RBV + Boceprevir	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600- 1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by boceprevir (800 mg, orally, 3 times per day) plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up.

Measured Values

	PegIFN-2b + RBV	PegIFN-2b + RBV + Boceprevir
Number of Participants Analyzed [units: participants]	**34**	**64**
Percentage of Participants With Early Virologic Response (EVR) Who Achieved SVR24 [units: percentage of participants]		
HCV-RNA undetectable at Week 2 (n=0, 0)	**0**	**0**
HCV-RNA undetectable at Week 4 (n=3, 3)	**100**	**100**
HCV-RNA undetectable at Week 8 (n=5, 27)	**100**	**92.6**
HCV-RNA undetectable at Week 12 (n=8, 38)	**87.5**	**92.1**

No statistical analysis provided for Percentage of Participants With Early Virologic Response (EVR) Who Achieved SVR24

4. Secondary: Percentage of Participants With Undetectable HCV-RNA at Follow-up Week 12 (FW12) [Time Frame: Up to Week 60]

Measure Type	Secondary
Measure Title	Percentage of Participants With Undetectable HCV-RNA at Follow-up Week 12 (FW12)
Measure Description	The virologic response at FW12 was considered SVR12 with an additional rule for handling missing data: participants with missing HCV-RNA assessment at FW12 but having non-missing, undetectable HCV-RNA assessments at both FW4 and FW24, were assumed to be responders for SVR12. HCV-RNA was detected by a nucleic acid amplification test and the lower limit of detection for this assay is 9.3 IU/mL.
Time Frame	Up to Week 60
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 randomized participants receiving at least one dose of any study medication (Full Analysis Set); this includes 3 participants who did not enter the Follow-Up Period.

Reporting Groups

	Description
PegIFN-2b + RBV	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600-1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by placebo to boceprevir plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up (Control Arm). Participants who do not achieve HCV-RNA <9.3 IU/mL by Treatment Week 24 (TW24) are eligible to cross-over and receive boceprevir along with the PegIFN-2b and RBV for up to 44 weeks.
PegIFN-2b + RBV + Boceprevir	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600- 1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by boceprevir (800 mg, orally, 3 times per day) plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up.

Measured Values

	PegIFN-2b + RBV	PegIFN-2b + RBV + Boceprevir
Number of Participants Analyzed	**34**	**64**

[units: participants]		
Percentage of Participants With Undetectable HCV-RNA at Follow-up Week 12 (FW12) **[units: percentage of participants]**	**26.5**	**62.5**

No statistical analysis provided for Percentage of Participants With Undetectable HCV-RNA at Follow-up Week 12 (FW12)

5. Secondary: Change From Baseline in log10 HCV-RNA at Treatment Week 4 (TW4) [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Change From Baseline in log10 HCV-RNA at Treatment Week 4 (TW4)
Measure Description	This is a measure of the change in the amount of HCV-RNA in the plasma at the end of 4 weeks of treatment. HCV-RNA was detected by a nucleic acid amplification test and the lower limit of detection for this assay is 9.3 IU/mL.
Time Frame	Baseline and Week 4
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 randomized participants receiving at least one dose of any study medication (Full Analysis Set); this includes 3 participants who did not enter the Follow-Up Period.

Reporting Groups

	Description
PegIFN-2b + RBV	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600-1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by placebo to boceprevir plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up (Control Arm). Participants who do not achieve HCV-RNA <9.3 IU/mL by Treatment Week 24 (TW24) are eligible to cross-over and receive boceprevir along with the PegIFN-2b and RBV for up to 44 weeks.
PegIFN-2b + RBV + Boceprevir	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600- 1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by boceprevir (800 mg, orally, 3 times per day) plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up.

Measured Values

	PegIFN-2b + RBV	**PegIFN-2b + RBV + Boceprevir**
Number of Participants Analyzed **[units: participants]**	**34**	**64**
Change From Baseline in log10 HCV-RNA at Treatment Week 4 (TW4) **[units: participants]**		
Participants with <1 positive log drop	**15**	**28**
Participants with >= 1 positive log drop	**16**	**32**
Participants with undetectable HCV-RNA	**3**	**3**
Participants with missing data	**0**	**1**

No statistical analysis provided for Change From Baseline in log10 HCV-RNA at Treatment Week 4 (TW4)

6. Secondary: Percentage of Participants With HCV Virologic Breakthrough or Incomplete Virologic Response/Rebound [Time Frame: Up to Week 72]

Measure Type	Secondary
Measure Title	Percentage of Participants With HCV Virologic Breakthrough or Incomplete Virologic Response/Rebound
Measure Description	Virologic breakthrough is defined as achieving undetectable HCV-RNA and subsequently having an HCV-RNA level of >1000 IU/mL. Incomplete Virologic Response/Rebound is defined as having a one log10 increase in HCV-RNA from the participant's nadir, with an HCV-RNA >1000 IU/mL. HCV-RNA was detected by a nucleic acid amplification test and the lower limit of detection for this assay is 9.3 IU/mL.
Time Frame	Up to Week 72
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 randomized participants receiving at least one dose of any study medication (Full Analysis Set); this includes 3 participants who did not enter the Follow-Up Period.

Reporting Groups

	Description
PegIFN-2b + RBV	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600-1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by placebo to boceprevir plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up (Control Arm). Participants who do not achieve HCV-RNA <9.3 IU/mL by Treatment Week 24 (TW24) are eligible to cross-over and receive boceprevir along with the PegIFN-2b and RBV for up to 44 weeks.
PegIFN-2b + RBV + Boceprevir	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600- 1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by boceprevir (800 mg, orally, 3 times per day) plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up.

Measured Values

	PegIFN-2b + RBV	**PegIFN-2b + RBV + Boceprevir**
Number of Participants Analyzed [units: participants]	**34**	**64**
Percentage of Participants With HCV Virologic Breakthrough or Incomplete Virologic Response/Rebound [units: percentage of participants]		
Virologic breakthrough	**0**	**6.3**
Incomplete response	**17.6**	**9.4**

No statistical analysis provided for Percentage of Participants With HCV Virologic Breakthrough or Incomplete Virologic Response/Rebound

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events were collected from randomization through Week 72.
Additional Description	One participant randomized to the boceprevir arm never received study drug. Adverse events for the 4 participants who crossed-over to boceprevir treatment at Treatment Week 24 (TW24) are included in the assigned treatment arm (PegIFN-2b + RBV) until TW24 and are presented separately for the period following the crossover.

Reporting Groups

	Description
PegIFN-2b+RBV	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600-1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by placebo to boceprevir plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up (Control Arm). Participants who do not achieve HCV-RNA <9.3 IU/mL by Treatment Week 24 (TW24) are eligible to cross-over and receive boceprevir along with the PegIFN-2b and RBV for up to 44 weeks.
PegIFN-2b+RBV+Boceprevir	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600- 1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by boceprevir (800 mg, orally, 3 times per day) plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up.
Boceprevir Crossover	(After Treatment Week 24) PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600- 1400 mg/day, orally, divided into two daily doses) plus boceprevir (800 mg, orally, 3 times per day) for up to 44 weeks with 24 weeks post-treatment follow-up.

Serious Adverse Events

	PegIFN-2b+RBV	PegIFN-2b+RBV+Boceprevir	Boceprevir Crossover
Total, serious adverse events			
# participants affected / at risk	**7/34 (20.59%)**	**11/64 (17.19%)**	**0/4 (0.00%)**
Blood and lymphatic system disorders			
ANAEMIA † 1			
# participants affected / at risk	**2/34 (5.88%)**	**2/64 (3.13%)**	**0/4 (0.00%)**
# events	**2**	**3**	**0**
LYMPHADENOPATHY † 1			
# participants affected / at risk	**0/34 (0.00%)**	**1/64 (1.56%)**	**0/4 (0.00%)**
# events	**0**	**1**	**0**
Cardiac disorders			
VENTRICULAR FIBRILLATION † 1			
# participants affected / at risk	**1/34 (2.94%)**	**0/64 (0.00%)**	**0/4 (0.00%)**
# events	**1**	**0**	**0**
Gastrointestinal disorders			
ABDOMINAL PAIN UPPER † 1			
# participants affected / at risk	**1/34 (2.94%)**	**0/64 (0.00%)**	**0/4 (0.00%)**
# events	**1**	**0**	**0**
PANCREATITIS † 1			
# participants affected / at risk	**1/34 (2.94%)**	**0/64 (0.00%)**	**0/4 (0.00%)**
# events	**1**	**0**	**0**
Hepatobiliary disorders			
CHOLELITHIASIS † 1			

# participants affected / at risk	1/34 (2.94%)	0/64 (0.00%)	0/4 (0.00%)
# events	1	0	0
Infections and infestations			
LUNG INFECTION PSEUDOMONAL † 1			
# participants affected / at risk	0/34 (0.00%)	1/64 (1.56%)	0/4 (0.00%)
# events	0	1	0
PELVIC INFLAMMATORY DISEASE † 1			
# participants affected / at risk	0/34 (0.00%)	1/64 (1.56%)	0/4 (0.00%)
# events	0	1	0
PNEUMONIA † 1			
# participants affected / at risk	0/34 (0.00%)	2/64 (3.13%)	0/4 (0.00%)
# events	0	2	0
POST PROCEDURAL INFECTION † 1			
# participants affected / at risk	1/34 (2.94%)	0/64 (0.00%)	0/4 (0.00%)
# events	1	0	0
SINUSITIS † 1			
# participants affected / at risk	0/34 (0.00%)	1/64 (1.56%)	0/4 (0.00%)
# events	0	1	0
URINARY TRACT INFECTION † 1			
# participants affected / at risk	0/34 (0.00%)	1/64 (1.56%)	0/4 (0.00%)
# events	0	1	0
VULVAL ABSCESS † 1			
# participants affected / at risk	1/34 (2.94%)	0/64 (0.00%)	0/4 (0.00%)
# events	1	0	0
Injury, poisoning and procedural complications			
LIGAMENT RUPTURE † 1			
# participants affected / at risk	1/34 (2.94%)	0/64 (0.00%)	0/4 (0.00%)
# events	1	0	0
MENISCUS LESION † 1			
# participants affected / at risk	1/34 (2.94%)	0/64 (0.00%)	0/4 (0.00%)
# events	1	0	0
OVERDOSE † 1			
# participants affected / at risk	1/34 (2.94%)	0/64 (0.00%)	0/4 (0.00%)
# events	1	0	0
Metabolism and nutrition disorders			
LACTIC ACIDOSIS † 1			
# participants affected / at risk	1/34 (2.94%)	0/64 (0.00%)	0/4 (0.00%)
# events	1	0	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA † 1			
# participants affected / at risk	0/34 (0.00%)	1/64 (1.56%)	0/4 (0.00%)
# events	0	1	0
Nervous system disorders			
† 1			

SYNCOPE			
# participants affected / at risk	**0/34 (0.00%)**	**1/64 (1.56%)**	**0/4 (0.00%)**
# events	**0**	**1**	**0**
Psychiatric disorders			
DEPRESSION † 1			
# participants affected / at risk	**0/34 (0.00%)**	**1/64 (1.56%)**	**0/4 (0.00%)**
# events	**0**	**1**	**0**
SUICIDE ATTEMPT † 1			
# participants affected / at risk	**0/34 (0.00%)**	**1/64 (1.56%)**	**0/4 (0.00%)**
# events	**0**	**1**	**0**
Renal and urinary disorders			
RENAL FAILURE † 1			
# participants affected / at risk	**1/34 (2.94%)**	**0/64 (0.00%)**	**0/4 (0.00%)**
# events	**1**	**0**	**0**
RENAL FAILURE ACUTE † 1			
# participants affected / at risk	**0/34 (0.00%)**	**1/64 (1.56%)**	**0/4 (0.00%)**
# events	**0**	**1**	**0**
Respiratory, thoracic and mediastinal disorders			
PULMONARY EMBOLISM † 1			
# participants affected / at risk	**0/34 (0.00%)**	**2/64 (3.13%)**	**0/4 (0.00%)**
# events	**0**	**2**	**0**
PULMONARY HYPERTENSION † 1			
# participants affected / at risk	**0/34 (0.00%)**	**1/64 (1.56%)**	**0/4 (0.00%)**
# events	**0**	**1**	**0**
RESPIRATORY FAILURE † 1			
# participants affected / at risk	**1/34 (2.94%)**	**0/64 (0.00%)**	**0/4 (0.00%)**
# events	**1**	**0**	**0**
Surgical and medical procedures			
CHOLECYSTECTOMY † 1			
# participants affected / at risk	**1/34 (2.94%)**	**0/64 (0.00%)**	**0/4 (0.00%)**
# events	**1**	**0**	**0**
Vascular disorders			
DEEP VEIN THROMBOSIS † 1			
# participants affected / at risk	**0/34 (0.00%)**	**1/64 (1.56%)**	**0/4 (0.00%)**
# events	**0**	**1**	**0**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 15.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events were collected from randomization through Week 72.
Additional Description	One participant randomized to the boceprevir arm never received study drug.

	Adverse events for the 4 participants who crossed-over to boceprevir treatment at Treatment Week 24 (TW24) are included in the assigned treatment arm (PegIFN-2b + RBV) until TW24 and are presented separately for the period following the crossover.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
PegIFN-2b+RBV	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600-1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by placebo to boceprevir plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up (Control Arm). Participants who do not achieve HCV-RNA <9.3 IU/mL by Treatment Week 24 (TW24) are eligible to cross-over and receive boceprevir along with the PegIFN-2b and RBV for up to 44 weeks.
PegIFN-2b+RBV+Boceprevir	PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600- 1400 mg/day, orally, divided into two daily doses) for 4 weeks followed by boceprevir (800 mg, orally, 3 times per day) plus PegIFN-2b/RBV for 44 weeks with 24 weeks post-treatment follow-up.
Boceprevir Crossover	(After Treatment Week 24) PegIFN-2b (1.5 µg/kg/week subcutaneously) plus RBV (600- 1400 mg/day, orally, divided into two daily doses) plus boceprevir (800 mg, orally, 3 times per day) for up to 44 weeks with 24 weeks post-treatment follow-up.

Other Adverse Events

	PegIFN-2b+RBV	PegIFN-2b+RBV+Boceprevir	Boceprevir Crossover
Total, other (not including serious) adverse events			
# participants affected / at risk	**33/34 (97.06%)**	**62/64 (96.88%)**	**4/4 (100.00%)**
Blood and lymphatic system disorders			
ANAEMIA † 1			
# participants affected / at risk	**8/34 (23.53%)**	**26/64 (40.63%)**	**2/4 (50.00%)**
# events	**8**	**40**	**2**
NEUTROPENIA † 1			
# participants affected / at risk	**2/34 (5.88%)**	**12/64 (18.75%)**	**1/4 (25.00%)**
# events	**2**	**14**	**1**
THROMBOCYTOPENIA † 1			
# participants affected / at risk	**0/34 (0.00%)**	**5/64 (7.81%)**	**1/4 (25.00%)**
# events	**0**	**5**	**1**
Cardiac disorders			
PALPITATIONS † 1			
# participants affected / at risk	**0/34 (0.00%)**	**2/64 (3.13%)**	**1/4 (25.00%)**
# events	**0**	**2**	**1**
Congenital, familial and genetic disorders			
PORPHYRIA † 1			
# participants affected / at risk	**0/34 (0.00%)**	**0/64 (0.00%)**	**1/4 (25.00%)**
# events	**0**	**0**	**1**
Eye disorders			
DRY EYE † 1			
# participants affected / at risk	**2/34 (5.88%)**	**2/64 (3.13%)**	**0/4 (0.00%)**

# events	2	3	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT † 1			
# participants affected / at risk	0/34 (0.00%)	2/64 (3.13%)	1/4 (25.00%)
# events	0	2	1
ABDOMINAL PAIN † 1			
# participants affected / at risk	3/34 (8.82%)	3/64 (4.69%)	0/4 (0.00%)
# events	3	3	0
ABDOMINAL PAIN UPPER † 1			
# participants affected / at risk	1/34 (2.94%)	6/64 (9.38%)	0/4 (0.00%)
# events	1	7	0
APHTHOUS STOMATITIS † 1			
# participants affected / at risk	0/34 (0.00%)	6/64 (9.38%)	0/4 (0.00%)
# events	0	6	0
CHEILITIS † 1			
# participants affected / at risk	2/34 (5.88%)	5/64 (7.81%)	1/4 (25.00%)
# events	2	6	1
CONSTIPATION † 1			
# participants affected / at risk	5/34 (14.71%)	4/64 (6.25%)	1/4 (25.00%)
# events	5	4	1
DIARRHOEA † 1			
# participants affected / at risk	6/34 (17.65%)	21/64 (32.81%)	0/4 (0.00%)
# events	8	30	0
DRY MOUTH † 1			
# participants affected / at risk	0/34 (0.00%)	5/64 (7.81%)	0/4 (0.00%)
# events	0	5	0
NAUSEA † 1			
# participants affected / at risk	11/34 (32.35%)	26/64 (40.63%)	1/4 (25.00%)
# events	12	37	1
ORAL PAIN † 1			
# participants affected / at risk	0/34 (0.00%)	4/64 (6.25%)	0/4 (0.00%)
# events	0	4	0
RECTAL HAEMORRHAGE † 1			
# participants affected / at risk	0/34 (0.00%)	0/64 (0.00%)	1/4 (25.00%)
# events	0	0	1
TONGUE DISCOLOURATION † 1			
# participants affected / at risk	2/34 (5.88%)	0/64 (0.00%)	0/4 (0.00%)
# events	2	0	0
VOMITING † 1			
# participants affected / at risk	5/34 (14.71%)	18/64 (28.13%)	0/4 (0.00%)
# events	9	23	0
General disorders			
ASTHENIA † 1			
# participants affected / at risk	9/34 (26.47%)	22/64 (34.38%)	2/4 (50.00%)
# events	9	30	2

CHILLS † 1			
# participants affected / at risk	**5/34 (14.71%)**	**5/64 (7.81%)**	**0/4 (0.00%)**
# events	**5**	**5**	**0**
FATIGUE † 1			
# participants affected / at risk	**12/34 (35.29%)**	**25/64 (39.06%)**	**0/4 (0.00%)**
# events	**15**	**35**	**0**
INFLUENZA LIKE ILLNESS † 1			
# participants affected / at risk	**13/34 (38.24%)**	**16/64 (25.00%)**	**0/4 (0.00%)**
# events	**29**	**24**	**0**
INJECTION SITE ERYTHEMA † 1			
# participants affected / at risk	**1/34 (2.94%)**	**4/64 (6.25%)**	**0/4 (0.00%)**
# events	**1**	**4**	**0**
IRRITABILITY † 1			
# participants affected / at risk	**5/34 (14.71%)**	**10/64 (15.63%)**	**1/4 (25.00%)**
# events	**5**	**11**	**1**
MALAISE † 1			
# participants affected / at risk	**2/34 (5.88%)**	**3/64 (4.69%)**	**0/4 (0.00%)**
# events	**2**	**3**	**0**
OEDEMA PERIPHERAL † 1			
# participants affected / at risk	**2/34 (5.88%)**	**3/64 (4.69%)**	**0/4 (0.00%)**
# events	**2**	**3**	**0**
PAIN † 1			
# participants affected / at risk	**1/34 (2.94%)**	**5/64 (7.81%)**	**0/4 (0.00%)**
# events	**1**	**5**	**0**
PYREXIA † 1			
# participants affected / at risk	**7/34 (20.59%)**	**24/64 (37.50%)**	**1/4 (25.00%)**
# events	**13**	**60**	**1**
Infections and infestations			
FOLLICULITIS † 1			
# participants affected / at risk	**2/34 (5.88%)**	**0/64 (0.00%)**	**0/4 (0.00%)**
# events	**2**	**0**	**0**
GINGIVAL ABSCESS † 1			
# participants affected / at risk	**0/34 (0.00%)**	**0/64 (0.00%)**	**1/4 (25.00%)**
# events	**0**	**0**	**1**
INFLUENZA † 1			
# participants affected / at risk	**4/34 (11.76%)**	**6/64 (9.38%)**	**0/4 (0.00%)**
# events	**5**	**7**	**0**
NASOPHARYNGITIS † 1			
# participants affected / at risk	**4/34 (11.76%)**	**5/64 (7.81%)**	**0/4 (0.00%)**
# events	**4**	**5**	**0**
ORAL CANDIDIASIS † 1			
# participants affected / at risk	**2/34 (5.88%)**	**3/64 (4.69%)**	**0/4 (0.00%)**
# events	**2**	**5**	**0**
RESPIRATORY TRACT INFECTION † 1			
# participants affected / at risk	**1/34 (2.94%)**	**2/64 (3.13%)**	**1/4 (25.00%)**

# events	1	3	1
SINUSITIS † 1			
# participants affected / at risk	0/34 (0.00%)	5/64 (7.81%)	1/4 (25.00%)
# events	0	6	1
UPPER RESPIRATORY TRACT INFECTION † 1			
# participants affected / at risk	2/34 (5.88%)	1/64 (1.56%)	0/4 (0.00%)
# events	2	1	0
URINARY TRACT INFECTION † 1			
# participants affected / at risk	2/34 (5.88%)	3/64 (4.69%)	0/4 (0.00%)
# events	2	3	0
Investigations			
GAMMA-GLUTAMYLTRANSFERASE INCREASED † 1			
# participants affected / at risk	2/34 (5.88%)	0/64 (0.00%)	0/4 (0.00%)
# events	2	0	0
TRANSAMINASES INCREASED † 1			
# participants affected / at risk	2/34 (5.88%)	0/64 (0.00%)	0/4 (0.00%)
# events	2	0	0
WEIGHT DECREASED † 1			
# participants affected / at risk	1/34 (2.94%)	8/64 (12.50%)	0/4 (0.00%)
# events	1	9	0
Metabolism and nutrition disorders			
DECREASED APPETITE † 1			
# participants affected / at risk	6/34 (17.65%)	22/64 (34.38%)	0/4 (0.00%)
# events	6	22	0
HYPERTRIGLYCERIDAEMIA † 1			
# participants affected / at risk	2/34 (5.88%)	2/64 (3.13%)	1/4 (25.00%)
# events	2	3	1
Musculoskeletal and connective tissue disorders			
ARTHRALGIA † 1			
# participants affected / at risk	2/34 (5.88%)	7/64 (10.94%)	0/4 (0.00%)
# events	2	7	0
MYALGIA † 1			
# participants affected / at risk	6/34 (17.65%)	9/64 (14.06%)	0/4 (0.00%)
# events	7	12	0
NECK PAIN † 1			
# participants affected / at risk	2/34 (5.88%)	2/64 (3.13%)	0/4 (0.00%)
# events	2	2	0
PAIN IN EXTREMITY † 1			
# participants affected / at risk	2/34 (5.88%)	3/64 (4.69%)	0/4 (0.00%)
# events	2	3	0
Nervous system disorders			
DIZZINESS † 1			
# participants affected / at risk	2/34 (5.88%)	8/64 (12.50%)	1/4 (25.00%)
# events	2	9	1

DYSGEUSIA † 1			
# participants affected / at risk	5/34 (14.71%)	18/64 (28.13%)	2/4 (50.00%)
# events	5	18	2
HEADACHE † 1			
# participants affected / at risk	6/34 (17.65%)	18/64 (28.13%)	0/4 (0.00%)
# events	6	63	0
PARAESTHESIA † 1			
# participants affected / at risk	2/34 (5.88%)	2/64 (3.13%)	0/4 (0.00%)
# events	2	2	0
SOMNOLENCE † 1			
# participants affected / at risk	1/34 (2.94%)	0/64 (0.00%)	1/4 (25.00%)
# events	1	0	1
Pregnancy, puerperium and perinatal conditions			
PREGNANCY † 1			
# participants affected / at risk	0/34 (0.00%)	0/64 (0.00%)	1/4 (25.00%)
# events	0	0	1
Psychiatric disorders			
AFFECT LABILITY † 1			
# participants affected / at risk	2/34 (5.88%)	1/64 (1.56%)	1/4 (25.00%)
# events	2	1	1
ANXIETY † 1			
# participants affected / at risk	5/34 (14.71%)	10/64 (15.63%)	0/4 (0.00%)
# events	8	11	0
APATHY † 1			
# participants affected / at risk	1/34 (2.94%)	0/64 (0.00%)	1/4 (25.00%)
# events	1	0	1
DEPRESSED MOOD † 1			
# participants affected / at risk	1/34 (2.94%)	1/64 (1.56%)	1/4 (25.00%)
# events	2	1	1
DEPRESSION † 1			
# participants affected / at risk	4/34 (11.76%)	11/64 (17.19%)	0/4 (0.00%)
# events	4	11	0
DRUG ABUSE † 1			
# participants affected / at risk	2/34 (5.88%)	0/64 (0.00%)	0/4 (0.00%)
# events	2	0	0
INSOMNIA † 1			
# participants affected / at risk	9/34 (26.47%)	15/64 (23.44%)	0/4 (0.00%)
# events	12	17	0
NERVOUSNESS † 1			
# participants affected / at risk	1/34 (2.94%)	1/64 (1.56%)	1/4 (25.00%)
# events	1	1	1
SLEEP DISORDER † 1			
# participants affected / at risk	1/34 (2.94%)	5/64 (7.81%)	0/4 (0.00%)
# events	1	5	0
Reproductive system and breast disorders			

METRORRHAGIA † 1			
# participants affected / at risk	2/34 (5.88%)	0/64 (0.00%)	0/4 (0.00%)
# events	2	0	0
Respiratory, thoracic and mediastinal disorders			
COUGH † 1			
# participants affected / at risk	6/34 (17.65%)	9/64 (14.06%)	0/4 (0.00%)
# events	6	10	0
DYSPNOEA † 1			
# participants affected / at risk	2/34 (5.88%)	5/64 (7.81%)	0/4 (0.00%)
# events	2	5	0
DYSPNOEA EXERTIONAL † 1			
# participants affected / at risk	2/34 (5.88%)	5/64 (7.81%)	0/4 (0.00%)
# events	2	5	0
OROPHARYNGEAL PAIN † 1			
# participants affected / at risk	2/34 (5.88%)	5/64 (7.81%)	0/4 (0.00%)
# events	2	7	0
PRODUCTIVE COUGH † 1			
# participants affected / at risk	2/34 (5.88%)	0/64 (0.00%)	0/4 (0.00%)
# events	2	0	0
Skin and subcutaneous tissue disorders			
ALOPECIA † 1			
# participants affected / at risk	6/34 (17.65%)	12/64 (18.75%)	0/4 (0.00%)
# events	6	12	0
DRY SKIN † 1			
# participants affected / at risk	3/34 (8.82%)	8/64 (12.50%)	0/4 (0.00%)
# events	4	11	0
ERYTHEMA † 1			
# participants affected / at risk	1/34 (2.94%)	4/64 (6.25%)	0/4 (0.00%)
# events	1	4	0
PRURITUS † 1			
# participants affected / at risk	3/34 (8.82%)	13/64 (20.31%)	1/4 (25.00%)
# events	4	16	1
RASH † 1			
# participants affected / at risk	0/34 (0.00%)	5/64 (7.81%)	0/4 (0.00%)
# events	0	5	0

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 15.0

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

No text entered.

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 Investigator must provide to the sponsor 45 days prior to submission for publication or presentation, review copies of abstracts or manuscripts for publication (including, without limitation, slides and texts of oral or other public presentations and texts of any transmission through any electronic media, eg, any computer access system such as the Internet, World Wide Web, etc.) that report any results of the trial. The sponsor shall have the right to review and comment.

Results Point of Contact:

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

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

Sulkowski M, Pol S, Mallolas J, Fainboim H, Cooper C, Slim J, Rivero A, Mak C, Thompson S, Howe AY, Wenning L, Sklar P, Wahl J, Greaves W; P05411 study investigators. Boceprevir versus placebo with pegylated interferon alfa-2b and ribavirin for treatment of hepatitis C virus genotype 1 in patients with HIV: a randomised, double-blind, controlled phase 2 trial. Lancet Infect Dis. 2013 Jul;13(7):597-605. doi: 10.1016/S1473-3099(13)70149-X. Epub 2013 Jun 12.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00959699 History of Changes
Other Study ID Numbers:	P05411 MK-3034-025 (Other Identifier: Merck study number)
Study First Received:	July 29, 2009
Results First Received:	May 8, 2013
Last Updated:	September 4, 2015
Health Authority:	United States: Food and Drug Administration

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

Copyright | Privacy | Accessibility | Viewers and Players | Freedom of Information Act | USA.gov
U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health and Human Services