Boceprevir in Subjects With Chronic Hepatitis C Genotype 1 Who Failed Prior Treatment With Peginterferon/Ribavirin (Study P05101AM3)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00708500

First received: June 27, 2008
Last updated: September 24, 2015
Last verified: September 2015
History of Changes

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

Purpose

This study involves treatment with boceprevir or placebo in combination with pegylated interferon alfa-2b (PegIntron, PEG2b) + Ribavirin (RBV) (weight-based dosing [WBD]) in adult subjects with chronic hepatitis C (CHC) genotype 1 who demonstrated interferon responsiveness (a decrease in hepatitis C virus RNA [HCV-RNA] viral load >=2 log10 by Week 12 or undetectable HCV-RNA at end of treatment) but who failed to achieve sustained virologic response (SVR) on prior treatment with any combination therapy of peginterferon alpha and RBV. This trial includes three arms, one control arm (PEG2b + RBV for 48 weeks) and two experimental arms (PEG2b + RBV + boceprevir). One of the experimental arms, Arm 3, consists of treatment with all three drugs for 44 weeks after the lead-in. The other experimental arm, Arm 2, consists of all three drugs for 32 weeks after the lead-in. Participants in Arm 2 who were undetectable for HCV-RNA at Treatment Week 8 will complete treatment at that point. Those who were not undetectable for HCV-RNA at Treatment Week 8 will receive an additional 12 weeks of PEG2b + RBV + boceprevir placebo. It is hypothesized that the addition of a third active anti-HCV drug may lead to more rapid viral response than therapy with two drugs, and therefore, the addition of boceprevir to PEG2b plus RBV therapy after a 4-week lead-in period may allow for both increased rates of SVR and shorter treatment durations (in some populations) than treatment with peginterferon plus RBV alone.

Condition	Intervention	Phase
Hepatitis C, Chronic	Drug: Boceprevir (SCH 503034) Biological: Pegylated interferon alfa-2b (SCH 54031) Drug: Ribavirin (SCH 18908) Drug: Boceprevir placebo	Phase 3

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

Official Title: A Phase 3 Safety and Efficacy Study of Boceprevir in Subjects With Chronic Hepatitis C Genotype 1 Who Failed Prior Treatment With Peginterferon/Ribavirin

Resource links provided by NLM:

MedlinePlus related topics: Hepatitis Hepatitis A Hepatitis C

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

U.S. FDA Resources

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

Primary Outcome Measures:

- Sustained Virologic Response (SVR) Rate in the Full Analysis Set (FAS) Population. [Time Frame: At Follow-up Week 24] [Designated as safety issue: No]

  SVR is defined as undetectable plasma hepatitis C virus RNA (HCV-RNA) at Follow-up Week 24. This outcome measure evaluates SVR after treatment with boceprevir and PEG2b plus RBV versus PEG2b plus RBV alone in participants with chronic hepatitis C (CHC) genotype 1 who failed prior treatment.

Secondary Outcome Measures:

- Sustained Virologic Response (SVR) Rate in the Modified Intent to Treat (mITT) Population. [Time Frame: At Follow-up Week 24] [Designated as safety issue: No]

  SVR is defined as undetectable plasma HCV-RNA at Follow-up Week 24. This outcome measure evaluates SVR after treatment with boceprevir and PEG2b plus RBV versus PEG2b plus RBV alone in participants with CHC genotype 1 who failed prior treatment.

  This key secondary efficacy endpoint was added as per the second protocol amendment on 02 DEC 2009.

- Number of Participants With Early Virologic Response. [Time Frame: At Week 2, 4, 8, or 12] [Designated as safety issue: No]

  Having undetectable HCV-RNA at Week 2, 4, 8, or 12 was considered Early Virologic Response.

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

Enrollment:	404
Study Start Date:	August 2008
Study Completion Date:	April 2010
Primary Completion Date:	April 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Placebo Comparator: Placebo+PEG2b+RBV, x 44 weeks Participants in Arm 1 (control) received pegylated interferon alfa 2b (PegIntron, PEG2b) + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by boceprevir placebo + PEG2b + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.	Biological: Pegylated interferon alfa-2b (SCH 54031) PEG2b 1.5 µg/kg/week subcutaneously (SC) Other Names: • PegIntron • PEG2b Drug: Ribavirin (SCH 18908) Ribavirin WBD 600 mg/day to 1400 mg/day by mouth (PO) divided twice daily (BID). Other Names: • Rebetol • RBV Drug: Boceprevir placebo Boceprevir placebo, 200 mg capsules, 800 mg three

	times daily (TID) PO.
Experimental: Boceprevir+PEG2b+RBV, Response Guided Therapy Participants in Arm 2 (experimental) were assigned either a 36-week or 48-week course of therapy based on their HCV-RNA status at Treatment Week 8. PEG2b + RBV (WBD) for 4 weeks followed by boceprevir + PEG2b + RBV (WBD) for 32 weeks, then: • 36-week regimen: Participants who have undetectable HCV-RNA at Treatment Week 8 discontinue treatment and enter 36 weeks of post treatment follow-up. • 48-week regimen: Participants who have detectable HCV-RNA at Treatment Week 8 are assigned an additional 12 weeks of therapy, followed by 24 weeks of post treatment follow-up. Placebo replaces boceprevir for the remaining 12 weeks of therapy, and this switch will occur in a blinded fashion.	Drug: Boceprevir (SCH 503034) Boceprevir, 200 mg capsules, 800 mg TID PO Biological: Pegylated interferon alfa-2b (SCH 54031) PEG2b 1.5 µg/kg/week subcutaneously (SC) Other Names: • PegIntron • PEG2b Drug: Ribavirin (SCH 18908) Ribavirin WBD 600 mg/day to 1400 mg/day by mouth (PO) divided twice daily (BID). Other Names: • Rebetol • RBV Drug: Boceprevir placebo Boceprevir placebo, 200 mg capsules, 800 mg three times daily (TID) PO.
Experimental: Boceprevir+PEG2b+RBV, x 44 weeks Participants in Arm 3 (experimental) received PEG2b + RBV (WBD) for 4 weeks followed by boceprevir + PEG2b + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.	Drug: Boceprevir (SCH 503034) Boceprevir, 200 mg capsules, 800 mg TID PO Biological: Pegylated interferon alfa-2b (SCH 54031) PEG2b 1.5 µg/kg/week subcutaneously (SC) Other Names: • PegIntron • PEG2b Drug: Ribavirin (SCH 18908) Ribavirin WBD 600 mg/day to 1400 mg/day by mouth (PO) divided twice daily (BID). Other Names: • Rebetol • RBV

Eligibility

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

Criteria

Inclusion Criteria:

- Qualifying regimen defined as pegylated interferon alfa-2a plus ribavirin or pegylated interferon alfa-2b plus ribavirin for a minimum of 12 weeks.
- During qualifying regimen, participants must have either a documented undetectable HCV-RNA within 30 days of end of treatment (EOT) and a subsequent detectable HCV-RNA during follow-up or a documented decline in HCV-RNA by >=2 log10 by Treatment Week 12
- Previously documented CHC genotype 1 infection.
- Liver biopsy with histology consistent with CHC and no other etiology.
- Participants with bridging fibrosis or cirrhosis must have an ultrasound within 6 months of the Screening Visit (or between Screening and Day 1) with no findings suspicious for hepatocellular carcinoma (HCC).
- Participants participating in Schering-Plough Research Institute (SPRI) maintenance protocols P02570 (NCT00049842) or P02569 (NCT00048724) must have completed the study to be eligible for this protocol.
- Participants must be >=18 years of age.
- Participants must weigh between 40 kg and 125 kg.
- Participants and participant's partner(s) must each agree to use acceptable methods of contraception for at least 2 weeks prior to Day 1 and continue until at least 6 months after last dose of study drug, or longer if dictated by local regulations.
- Participants must be willing to give written informed consent.

Exclusion Criteria:

- Coinfection with the human immunodeficiency virus (HIV) or hepatitis B virus (Hepatitis B Surface Antigen [HBsAg] positive).
- Discontinuation of previous interferon or ribavirin regimen for an adverse event (AE) considered by the investigator to be possibly or probably related to ribavirin and/or interferon.
- Treatment with ribavirin within 90 days and any interferon-alpha within 1 month of Screening.
- Treatment for hepatitis C with any investigational medication. Prior treatment with herbal remedies with known hepatotoxicity.
- Treatment with any investigational drug within 30 days of the randomization visit.
- Participation in any other clinical trial within 30 days of randomization or intention to participate in another clinical trial.
- Evidence of decompensated liver disease including, but not limited to, a history or presence of clinical ascites, bleeding varices, or hepatic encephalopathy.
- Diabetic and/or hypertensive participants with clinically significant ocular examination findings.
- Pre-existing psychiatric conditions.
- Clinical diagnosis of substance abuse of the specified drugs within the specified timeframes
- Any known pre-existing medical condition that could interfere with the participant's participation in and completion of the study.
- Evidence of active or suspected malignancy, or a history of malignancy, within the last 5 years (except adequately treated carcinoma in situ and basal cell carcinoma of the skin). Participants under evaluation for malignancy are not eligible.
- Participants who are pregnant or nursing. Participants who intend to become pregnant during the study period. Male participants with partners who are, or intend to become, pregnant during the study period.
- Any other condition which, in the opinion of a physician, would make the participant unsuitable for enrollment or could interfere with the participant participating in and completing the study.
- Participants who are part of the site personnel directly involved with this study.
- Participants who are family members of the investigational study staff.
- Participants who had life-threatening serious adverse event (SAE) during screening period.
- Protocol-specified hematologic, biochemical, and serologic criteria: Hemoglobin <12 g/dL for females and <13 g/dL for males; Neutrophils <1500/mm^3 (Blacks: <1200/mm^3); Platelets <100,000/mm^3; Direct bilirubin >1.5 x upper limit of normal (ULN).
- Serum albumin <lower limit of normal (LLN)
- Thyroid-stimulating hormone (TSH) >1.2 x ULN or <0.8 x LLN of laboratory reference range, with certain exceptions.
- Serum creatinine >ULN of the laboratory reference.
- Protocol-specified serum glucose concentrations.
- Protocol-specified alpha fetoprotein range.
- Prothrombin Time/Partial Thromboplastin Time (PT/PTT) values >10% above laboratory reference range.
- Anti-nuclear antibodies (ANA) >1:320.

Contacts and Locations

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

No Contacts or Locations Provided

More Information

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

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

Bacon BR, Gordon SC, Lawitz E, Marcellin P, Vierling JM, Zeuzem S, Poordad F, Goodman ZD, Sings HL, Boparai N, Burroughs M, Brass CA, Albrecht JK, Esteban R; HCV RESPOND-2 Investigators. Boceprevir for previously treated chronic HCV genotype 1 infection. N Engl J Med. 2011 Mar 31;364(13):1207-17. doi: 10.1056/NEJMoa1009482.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00708500 History of Changes
Other Study ID Numbers:	P05101 2007-005151-42
Study First Received:	June 27, 2008
Results First Received:	May 13, 2011
Last Updated:	September 24, 2015
Health Authority:	United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
Treatment failure

Additional relevant MeSH terms:

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

ClinicalTrials.gov processed this record on May 08, 2016

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

Boceprevir in Subjects With Chronic Hepatitis C Genotype 1 Who Failed Prior Treatment With Peginterferon/Ribavirin (Study P05101AM3)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00708500

First received: June 27, 2008
Last updated: September 24, 2015
Last verified: September 2015
History of Changes

Results First Received: May 13, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Hepatitis C, Chronic
Interventions:	Drug: Boceprevir (SCH 503034) Biological: Pegylated interferon alfa-2b (SCH 54031) Drug: Ribavirin (SCH 18908) Drug: Boceprevir placebo

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
154 participants who discontinued during the treatment phase (including those from lead in and/or boceprevir/placebo) entered the follow up phase

Reporting Groups

	Description
Placebo+PEG2b+RBV, x 44 Weeks	Participants in Arm 1 (control) received pegylated interferon alfa 2b (PegIntron, PEG2b) + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by boceprevir placebo + PEG2b + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Boceprevir+PEG2b+RBV, Response Guided Therapy	Participants in Arm 2 (experimental) were assigned either a 36-week or 48-week course of therapy based on their HCV-RNA status at Treatment Week 8. PEG2b + RBV (WBD) for 4 weeks followed by boceprevir + PEG2b + RBV (WBD) for 32 weeks, then: • 36-week regimen: Participants who have undetectable HCV-RNA at Treatment Week 8 discontinue treatment and enter 36 weeks of post treatment follow-up. • 48-week regimen: Participants who have detectable HCV-RNA at Treatment Week 8 are assigned an additional 12 weeks of therapy, followed by 24 weeks of post treatment follow-up. Placebo replaces boceprevir for the remaining 12 weeks of therapy, and this switch will occur in a blinded fashion.
Boceprevir+PEG2b+RBV, x 44 Weeks	Participants in Arm 3 (experimental) received PEG2b + RBV (WBD) for 4 weeks followed by boceprevir + PEG2b + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.

Participant Flow for 3 periods

Period 1: Treatment (Tx): 4 WEEK LEAD-IN PERIOD

	Placebo+PEG2b+RBV, x 44 Weeks	Boceprevir+PEG2b+RBV, Response Guided Therapy	Boceprevir+PEG2b+RBV, x 44 Weeks
STARTED	80	162	162
Treated With PEG2b + RBV	80	162	161
COMPLETED	78	156	160
NOT COMPLETED	2	6	2
Adverse Event	1	3	1
Subject withdrawal unrelated to Tx	1	0	0
Subject withdrawal related to Tx	0	1	0
Subject withdrew consent	0	2	0
Randomized but not treated	0	0	1

Period 2: Tx: RECEIVING BOCEPREVIR/PLACEBO

	Placebo+PEG2b+RBV, x 44 Weeks	Boceprevir+PEG2b+RBV, Response Guided Therapy	Boceprevir+PEG2b+RBV, x 44 Weeks
STARTED	78	156	160
COMPLETED	23	104	105
NOT COMPLETED	55	52	55
Adverse Event	1	10	19
Treatment Failure	49	36	29
Lost to Follow-up	0	1	0

Subject withdrawal unrelated to Tx	**3**	**1**	**4**
Subject withdrawal related to Tx	**2**	**0**	**1**
Subject withdrew consent	**0**	**2**	**1**
Non-compliance with protocol	**0**	**1**	**1**
Administrative	**0**	**1**	**0**

Period 3: FOLLOWUP

	Placebo+PEG2b+RBV, x 44 Weeks	Boceprevir+PEG2b+RBV, Response Guided Therapy	Boceprevir+PEG2b+RBV, x 44 Weeks
STARTED	**77**	**151**	**158**
COMPLETED	**37**	**136**	**143**
NOT COMPLETED	**40**	**15**	**15**
Adverse Event	**0**	**1**	**0**
Lost to Follow-up	**1**	**6**	**4**
Subject withdrawal unrelated to Tx	**3**	**4**	**5**
Subject withdrew consent	**31**	**4**	**5**
Non-compliance with protocol	**5**	**0**	**1**

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
Placebo+PEG2b+RBV, x 44 Weeks	Participants in Arm 1 (control) received pegylated interferon alfa 2b (PegIntron, PEG2b) + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by boceprevir placebo + PEG2b + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Boceprevir+PEG2b+RBV, Response Guided Therapy	Participants in Arm 2 (experimental) were assigned either a 36-week or 48-week course of therapy based on their HCV-RNA status at Treatment Week 8. PEG2b + RBV (WBD) for 4 weeks followed by boceprevir + PEG2b + RBV (WBD) for 32 weeks, then: • 36-week regimen: Participants who have undetectable HCV-RNA at Treatment Week 8 discontinue treatment and enter 36 weeks of post treatment follow-up. • 48-week regimen: Participants who have detectable HCV-RNA at Treatment Week 8 are assigned an additional 12 weeks of therapy, followed by 24 weeks of post treatment follow-up. Placebo replaces boceprevir for the remaining 12 weeks of therapy, and this switch will occur in a blinded fashion.

Boceprevir+PEG2b+RBV, x 44 Weeks	Participants in Arm 3 (experimental) received PEG2b + RBV (WBD) for 4 weeks followed by boceprevir + PEG2b + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Total	Total of all reporting groups

Baseline Measures

	Placebo+PEG2b+RBV, x 44 Weeks	Boceprevir+PEG2b+RBV, Response Guided Therapy	Boceprevir+PEG2b+RBV, x 44 Weeks	Total
Number of Participants [units: participants]	**80**	**162**	**161**	**403**
Age [units: years] Mean (Standard Deviation)	**52.9 (8.1)**	**52.9 (7.4)**	**52.3 (7.7)**	**52.7 (7.7)**
Gender [units: participants]				
Female	**22**	**64**	**49**	**135**
Male	**58**	**98**	**112**	**268**

Outcome Measures

Hide All Outcome Measures

1. Primary: Sustained Virologic Response (SVR) Rate in the Full Analysis Set (FAS) Population. [Time Frame: At Follow-up Week 24]

Measure Type	Primary
Measure Title	Sustained Virologic Response (SVR) Rate in the Full Analysis Set (FAS) Population.
Measure Description	SVR is defined as undetectable plasma hepatitis C virus RNA (HCV-RNA) at Follow-up Week 24. This outcome measure evaluates SVR after treatment with boceprevir and PEG2b plus RBV versus PEG2b plus RBV alone in participants with chronic hepatitis C (CHC) genotype 1 who failed prior treatment.
Time Frame	At Follow-up Week 24
Safety Issue	No

Population Description

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

Reporting Groups

	Description
Placebo+PEG2b+RBV, x 44 Weeks	Participants in Arm 1 (control) received pegylated interferon alfa 2b (PegIntron, PEG2b) + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by boceprevir placebo + PEG2b + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Boceprevir+PEG2b+RBV, Response Guided Therapy	Participants in Arm 2 (experimental) were assigned either a 36-week or 48-week course of therapy based on their HCV-RNA status at Treatment Week 8. PEG2b + RBV (WBD) for 4 weeks followed by boceprevir + PEG2b + RBV (WBD) for 32 weeks, then:

	• 36-week regimen: Participants who have undetectable HCV-RNA at Treatment Week 8 discontinue treatment and enter 36 weeks of post treatment follow-up. • 48-week regimen: Participants who have detectable HCV-RNA at Treatment Week 8 are assigned an additional 12 weeks of therapy, followed by 24 weeks of post treatment follow-up. Placebo replaces boceprevir for the remaining 12 weeks of therapy, and this switch will occur in a blinded fashion.
Boceprevir+PEG2b+RBV, x 44 Weeks	Participants in Arm 3 (experimental) received PEG2b + RBV (WBD) for 4 weeks followed by boceprevir + PEG2b + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.

Measured Values

	Placebo+PEG2b+RBV, x 44 Weeks	Boceprevir+PEG2b+RBV, Response Guided Therapy	Boceprevir+PEG2b+RBV, x 44 Weeks
Number of Participants Analyzed [units: participants]	**80**	**162**	**161**
Sustained Virologic Response (SVR) Rate in the Full Analysis Set (FAS) Population. [units: Percentage of Participants]	**21.3**	**58.6**	**66.5**

Statistical Analysis 1 for Sustained Virologic Response (SVR) Rate in the Full Analysis Set (FAS) Population.

Groups [1]	Placebo+PEG2b+RBV, x 44 Weeks vs. Boceprevir+PEG2b+RBV, Response Guided Therapy
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.0001
Treatment Difference [4]	37.4
95% Confidence Interval	25.7 to 49.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	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:
	No text entered.
[4]	Other relevant estimation information:
	Difference in percentage of participants who achieved SVR: experimental minus control.

Statistical Analysis 2 for Sustained Virologic Response (SVR) Rate in the Full Analysis Set (FAS) Population.

Groups [1]	Placebo+PEG2b+RBV, x 44 Weeks vs. Boceprevir+PEG2b+RBV, x 44 Weeks
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.0001
Treatment Difference [4]	45.2

95% Confidence Interval	33.7 to 56.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	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:
	No text entered.
[4]	Other relevant estimation information:
	Difference in percentage of participants who achieved SVR: experimental minus control.

2. Secondary: Sustained Virologic Response (SVR) Rate in the Modified Intent to Treat (mITT) Population. [Time Frame: At Follow-up Week 24]

Measure Type	Secondary
Measure Title	Sustained Virologic Response (SVR) Rate in the Modified Intent to Treat (mITT) Population.
Measure Description	SVR is defined as undetectable plasma HCV-RNA at Follow-up Week 24. This outcome measure evaluates SVR after treatment with boceprevir and PEG2b plus RBV versus PEG2b plus RBV alone in participants with CHC genotype 1 who failed prior treatment. This key secondary efficacy endpoint was added as per the second protocol amendment on 02 DEC 2009.
Time Frame	At Follow-up Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
mITT = all randomized subjects who received at least one dose of boceprevir (experimental arms) or boceprevir placebo (control arm).

Reporting Groups

	Description
Placebo+PEG2b+RBV, x 44 Weeks	Participants in Arm 1 (control) received pegylated interferon alfa 2b (PegIntron, PEG2b) + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by boceprevir placebo + PEG2b + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Boceprevir+PEG2b+RBV, Response Guided Therapy	Participants in Arm 2 (experimental) were assigned either a 36-week or 48-week course of therapy based on their HCV-RNA status at Treatment Week 8. PEG2b + RBV (WBD) for 4 weeks followed by boceprevir + PEG2b + RBV (WBD) for 32 weeks, then: • 36-week regimen: Participants who have undetectable HCV-RNA at Treatment Week 8 discontinue treatment and enter 36 weeks of post treatment follow-up. • 48-week regimen: Participants who have detectable HCV-RNA at Treatment Week 8 are assigned an additional 12 weeks of therapy, followed by 24 weeks of post treatment follow-up. Placebo replaces boceprevir for the remaining 12 weeks of therapy, and this switch will occur in a blinded fashion.
Boceprevir+PEG2b+RBV, x 44 Weeks	Participants in Arm 3 (experimental) received PEG2b + RBV (WBD) for 4 weeks followed by boceprevir + PEG2b + RBV (WBD) for 44 weeks with 24 weeks post-

	treatment follow-up.

Measured Values

	Placebo+PEG2b+RBV, x 44 Weeks	Boceprevir+PEG2b+RBV, Response Guided Therapy	Boceprevir+PEG2b+RBV, x 44 Weeks
Number of Participants Analyzed [units: participants]	**78**	**156**	**160**
Sustained Virologic Response (SVR) Rate in the Modified Intent to Treat (mITT) Population. [units: Percentage of Participants]	**21.8**	**60.9**	**66.9**

Statistical Analysis 1 for Sustained Virologic Response (SVR) Rate in the Modified Intent to Treat (mITT) Population.

Groups [1]	Placebo+PEG2b+RBV, x 44 Weeks vs. Boceprevir+PEG2b+RBV, Response Guided Therapy
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.0001
Treatment Difference [4]	39.1
95% Confidence Interval	27.2 to 51.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	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:
	No text entered.
[4]	Other relevant estimation information:
	Difference in percentage of participants who achieved SVR: experimental minus control.

Statistical Analysis 2 for Sustained Virologic Response (SVR) Rate in the Modified Intent to Treat (mITT) Population.

Groups [1]	Placebo+PEG2b+RBV, x 44 Weeks vs. Boceprevir+PEG2b+RBV, x 44 Weeks
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.0001
Treatment Difference [4]	45.1
95% Confidence Interval	33.4 to 56.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	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:
	No text entered.
[4]	Other relevant estimation information:
	Difference in percentage of participants who achieved SVR: experimental minus control.

3. Secondary: Number of Participants With Early Virologic Response. [Time Frame: At Week 2, 4, 8, or 12]

Measure Type	Secondary
Measure Title	Number of Participants With Early Virologic Response.
Measure Description	Having undetectable HCV-RNA at Week 2, 4, 8, or 12 was considered Early Virologic Response.
Time Frame	At Week 2, 4, 8, or 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.
FAS = all randomized subjects who received at least one dose of any study medication (Peg, RBV, or boceprevir/placebo).

Reporting Groups

	Description
Placebo+PEG2b+RBV, x 44 Weeks	Participants in Arm 1 (control) received pegylated interferon alfa 2b (PegIntron, PEG2b) + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by boceprevir placebo + PEG2b + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Boceprevir+PEG2b+RBV, Response Guided Therapy	Participants in Arm 2 (experimental) were assigned either a 36-week or 48-week course of therapy based on their HCV-RNA status at Treatment Week 8. PEG2b + RBV (WBD) for 4 weeks followed by boceprevir + PEG2b + RBV (WBD) for 32 weeks, then: • 36-week regimen: Participants who have undetectable HCV-RNA at Treatment Week 8 discontinue treatment and enter 36 weeks of post treatment follow-up. • 48-week regimen: Participants who have detectable HCV-RNA at Treatment Week 8 are assigned an additional 12 weeks of therapy, followed by 24 weeks of post treatment follow-up. Placebo replaces boceprevir for the remaining 12 weeks of therapy, and this switch will occur in a blinded fashion.
Boceprevir+PEG2b+RBV, x 44 Weeks	Participants in Arm 3 (experimental) received PEG2b + RBV (WBD) for 4 weeks followed by boceprevir + PEG2b + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.

Measured Values

	Placebo+PEG2b+RBV, x 44 Weeks	**Boceprevir+PEG2b+RBV, Response Guided Therapy**	**Boceprevir+PEG2b+RBV, x 44 Weeks**
Number of Participants Analyzed [units: participants]	**80**	**162**	**161**
Number of Participants With Early Virologic Response. [units: participants]			

Week 2	**0**	**0**	**0**
Week 4	**2**	**0**	**2**
Week 8	**7**	**74**	**84**
Week 12	**23**	**111**	**121**

No statistical analysis provided for Number of Participants With Early Virologic Response.

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

Measure Type	Secondary
Measure Title	Number of Participants With Undetectable HCV-RNA at Follow-up Week 12 and at 72 Weeks After Randomization.
Measure Description	No text entered.
Time Frame	At Follow-up Week 12 and at 72 weeks after randomization
Safety Issue	No

Population Description

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

Reporting Groups

	Description
Placebo+PEG2b+RBV, x 44 Weeks	Participants in Arm 1 (control) received pegylated interferon alfa 2b (PegIntron, PEG2b) + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by boceprevir placebo + PEG2b + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Boceprevir+PEG2b+RBV, Response Guided Therapy	Participants in Arm 2 (experimental) were assigned either a 36-week or 48-week course of therapy based on their HCV-RNA status at Treatment Week 8. PEG2b + RBV (WBD) for 4 weeks followed by boceprevir + PEG2b + RBV (WBD) for 32 weeks, then: • 36-week regimen: Participants who have undetectable HCV-RNA at Treatment Week 8 discontinue treatment and enter 36 weeks of post treatment follow-up. • 48-week regimen: Participants who have detectable HCV-RNA at Treatment Week 8 are assigned an additional 12 weeks of therapy, followed by 24 weeks of post treatment follow-up. Placebo replaces boceprevir for the remaining 12 weeks of therapy, and this switch will occur in a blinded fashion.
Boceprevir+PEG2b+RBV, x 44 Weeks	Participants in Arm 3 (experimental) received PEG2b + RBV (WBD) for 4 weeks followed by boceprevir + PEG2b + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.

Measured Values

	Placebo+PEG2b+RBV, x 44 Weeks	**Boceprevir+PEG2b+RBV, Response Guided Therapy**	**Boceprevir+PEG2b+RBV, x 44 Weeks**
Number of Participants Analyzed [units: participants]	**80**	**162**	**161**

Number of Participants With Undetectable HCV-RNA at Follow-up Week 12 and at 72 Weeks After Randomization. [units: participants]			
Follow-Up Week 12	16	97	105
72 Weeks Post Randomization	17	93	105

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

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Placebo+PEG2b+RBV, x 44 Weeks	Participants in Arm 1 (control) received pegylated interferon alfa 2b (PegIntron, PEG2b) + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by boceprevir placebo + PEG2b + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Boceprevir+PEG2b+RBV, Response Guided Therapy	Participants in Arm 2 (experimental) were assigned either a 36-week or 48-week course of therapy based on their HCV-RNA status at Treatment Week 8. PEG2b + RBV (WBD) for 4 weeks followed by boceprevir + PEG2b + RBV (WBD) for 32 weeks, then: • 36-week regimen: Participants who have undetectable HCV-RNA at Treatment Week 8 discontinue treatment and enter 36 weeks of post treatment follow-up. • 48-week regimen: Participants who have detectable HCV-RNA at Treatment Week 8 are assigned an additional 12 weeks of therapy, followed by 24 weeks of post treatment follow-up. Placebo replaces boceprevir for the remaining 12 weeks of therapy, and this switch will occur in a blinded fashion.
Boceprevir+PEG2b+RBV, x 44 Weeks	Participants in Arm 3 (experimental) received PEG2b + RBV (WBD) for 4 weeks followed by boceprevir + PEG2b + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.

Serious Adverse Events

	Placebo+PEG2b+RBV, x 44 Weeks	Boceprevir+PEG2b+RBV, Response Guided Therapy	Boceprevir+PEG2b+RBV, x 44 Weeks
Total, serious adverse events			
# participants affected / at risk	**4/80 (5.00%)**	**16/162 (9.88%)**	**23/161 (14.29%)**
Blood and lymphatic system disorders			
ANAEMIA † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**5/161 (3.11%)**
# events	**0**	**0**	**5**

Cardiac disorders			
ANGINA PECTORIS † 1			
# participants affected / at risk	**0/80 (0.00%)**	**1/162 (0.62%)**	**0/161 (0.00%)**
# events	**0**	**1**	**0**
ATRIAL FIBRILLATION † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**1/161 (0.62%)**
# events	**0**	**0**	**1**
CORONARY ARTERY DISEASE † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**1/161 (0.62%)**
# events	**0**	**0**	**1**
MYOCARDIAL INFARCTION † 1			
# participants affected / at risk	**0/80 (0.00%)**	**1/162 (0.62%)**	**0/161 (0.00%)**
# events	**0**	**1**	**0**
MYOPERICARDITIS † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**1/161 (0.62%)**
# events	**0**	**0**	**1**
Gastrointestinal disorders			
ABDOMINAL PAIN † 1			
# participants affected / at risk	**0/80 (0.00%)**	**2/162 (1.23%)**	**0/161 (0.00%)**
# events	**0**	**2**	**0**
CONSTIPATION † 1			
# participants affected / at risk	**0/80 (0.00%)**	**1/162 (0.62%)**	**0/161 (0.00%)**
# events	**0**	**1**	**0**
DIARRHOEA † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**1/161 (0.62%)**
# events	**0**	**0**	**1**
GASTRITIS † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**1/161 (0.62%)**
# events	**0**	**0**	**1**
IRRITABLE BOWEL SYNDROME † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**1/161 (0.62%)**
# events	**0**	**0**	**1**
OESOPHAGEAL VARICES HAEMORRHAGE † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**1/161 (0.62%)**
# events	**0**	**0**	**1**
PANCREATITIS ACUTE † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**1/161 (0.62%)**
# events	**0**	**0**	**1**
PANCREATITIS NECROTISING † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**1/161 (0.62%)**
# events	**0**	**0**	**1**
PEPTIC ULCER † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**1/161 (0.62%)**
# events	**0**	**0**	**1**

General disorders			
ASTHENIA † 1			
# participants affected / at risk	**0/80 (0.00%)**	**1/162 (0.62%)**	**0/161 (0.00%)**
# events	**0**	**1**	**0**
CHEST PAIN † 1			
# participants affected / at risk	**1/80 (1.25%)**	**2/162 (1.23%)**	**1/161 (0.62%)**
# events	**1**	**3**	**1**
OEDEMA PERIPHERAL † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**1/161 (0.62%)**
# events	**0**	**0**	**1**
PYREXIA † 1			
# participants affected / at risk	**0/80 (0.00%)**	**1/162 (0.62%)**	**0/161 (0.00%)**
# events	**0**	**1**	**0**
Hepatobiliary disorders			
CHOLECYSTITIS † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**1/161 (0.62%)**
# events	**0**	**0**	**2**
CHOLELITHIASIS † 1			
# participants affected / at risk	**1/80 (1.25%)**	**0/162 (0.00%)**	**0/161 (0.00%)**
# events	**2**	**0**	**0**
Infections and infestations			
APPENDICITIS † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**3/161 (1.86%)**
# events	**0**	**0**	**3**
BRONCHOPNEUMONIA † 1			
# participants affected / at risk	**0/80 (0.00%)**	**1/162 (0.62%)**	**0/161 (0.00%)**
# events	**0**	**1**	**0**
CATHETER SITE INFECTION † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**1/161 (0.62%)**
# events	**0**	**0**	**1**
GASTROENTERITIS † 1			
# participants affected / at risk	**1/80 (1.25%)**	**0/162 (0.00%)**	**0/161 (0.00%)**
# events	**1**	**0**	**0**
GASTROENTERITIS VIRAL † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**1/161 (0.62%)**
# events	**0**	**0**	**1**
PNEUMONIA † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**1/161 (0.62%)**
# events	**0**	**0**	**1**
Injury, poisoning and procedural complications			
LOWER LIMB FRACTURE † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**1/161 (0.62%)**
# events	**0**	**0**	**1**
OVERDOSE † 1			

# participants affected / at risk	0/80 (0.00%)	0/162 (0.00%)	1/161 (0.62%)
# events	0	0	1
Metabolism and nutrition disorders			
DECREASED APPETITE † 1			
# participants affected / at risk	0/80 (0.00%)	1/162 (0.62%)	0/161 (0.00%)
# events	0	1	0
DEHYDRATION † 1			
# participants affected / at risk	0/80 (0.00%)	0/162 (0.00%)	1/161 (0.62%)
# events	0	0	1
HYPERGLYCAEMIA † 1			
# participants affected / at risk	0/80 (0.00%)	0/162 (0.00%)	1/161 (0.62%)
# events	0	0	1
Musculoskeletal and connective tissue disorders			
BACK PAIN † 1			
# participants affected / at risk	0/80 (0.00%)	1/162 (0.62%)	0/161 (0.00%)
# events	0	1	0
INTERVERTEBRAL DISC PROTRUSION † 1			
# participants affected / at risk	0/80 (0.00%)	2/162 (1.23%)	0/161 (0.00%)
# events	0	2	0
PAIN IN EXTREMITY † 1			
# participants affected / at risk	0/80 (0.00%)	0/162 (0.00%)	1/161 (0.62%)
# events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
HEPATIC NEOPLASM MALIGNANT † 1			
# participants affected / at risk	0/80 (0.00%)	0/162 (0.00%)	1/161 (0.62%)
# events	0	0	1
Nervous system disorders			
HEPATIC ENCEPHALOPATHY † 1			
# participants affected / at risk	0/80 (0.00%)	0/162 (0.00%)	1/161 (0.62%)
# events	0	0	1
PARKINSONISM † 1			
# participants affected / at risk	1/80 (1.25%)	0/162 (0.00%)	0/161 (0.00%)
# events	1	0	0
SCIATICA † 1			
# participants affected / at risk	0/80 (0.00%)	1/162 (0.62%)	0/161 (0.00%)
# events	0	1	0
SYNCOPE † 1			
# participants affected / at risk	0/80 (0.00%)	1/162 (0.62%)	0/161 (0.00%)
# events	0	1	0
Psychiatric disorders			
BIPOLAR DISORDER † 1			
# participants affected / at risk	0/80 (0.00%)	0/162 (0.00%)	1/161 (0.62%)
# events	0	0	1

COMPLETED SUICIDE † 1			
# participants affected / at risk	**0/80 (0.00%)**	**1/162 (0.62%)**	**0/161 (0.00%)**
# events	**0**	**1**	**0**
DEPRESSION † 1			
# participants affected / at risk	**0/80 (0.00%)**	**3/162 (1.85%)**	**1/161 (0.62%)**
# events	**0**	**3**	**1**
HOMICIDAL IDEATION † 1			
# participants affected / at risk	**0/80 (0.00%)**	**1/162 (0.62%)**	**1/161 (0.62%)**
# events	**0**	**1**	**1**
SUICIDAL IDEATION † 1			
# participants affected / at risk	**0/80 (0.00%)**	**3/162 (1.85%)**	**2/161 (1.24%)**
# events	**0**	**3**	**2**
Respiratory, thoracic and mediastinal disorders			
DYSPNOEA † 1			
# participants affected / at risk	**0/80 (0.00%)**	**2/162 (1.23%)**	**0/161 (0.00%)**
# events	**0**	**2**	**0**
PLEURITIC PAIN † 1			
# participants affected / at risk	**0/80 (0.00%)**	**1/162 (0.62%)**	**0/161 (0.00%)**
# events	**0**	**1**	**0**
PNEUMOTHORAX † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**1/161 (0.62%)**
# events	**0**	**0**	**1**
Surgical and medical procedures			
ABDOMINAL HERNIA REPAIR † 1			
# participants affected / at risk	**0/80 (0.00%)**	**1/162 (0.62%)**	**0/161 (0.00%)**
# events	**0**	**1**	**0**
Vascular disorders			
DEEP VEIN THROMBOSIS † 1			
# participants affected / at risk	**0/80 (0.00%)**	**0/162 (0.00%)**	**1/161 (0.62%)**
# events	**0**	**0**	**1**
PHLEBITIS † 1			
# participants affected / at risk	**0/80 (0.00%)**	**1/162 (0.62%)**	**0/161 (0.00%)**
# events	**0**	**1**	**0**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 13.0

Other Adverse Events

Hide Other Adverse Events

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

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Placebo+PEG2b+RBV, x 44 Weeks	Participants in Arm 1 (control) received pegylated interferon alfa 2b (PegIntron, PEG2b) + Ribavirin (RBV) (weight-based dosing [WBD]) for 4 weeks followed by boceprevir placebo + PEG2b + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.
Boceprevir+PEG2b+RBV, Response Guided Therapy	Participants in Arm 2 (experimental) were assigned either a 36-week or 48-week course of therapy based on their HCV-RNA status at Treatment Week 8. PEG2b + RBV (WBD) for 4 weeks followed by boceprevir + PEG2b + RBV (WBD) for 32 weeks, then: • 36-week regimen: Participants who have undetectable HCV-RNA at Treatment Week 8 discontinue treatment and enter 36 weeks of post treatment follow-up. • 48-week regimen: Participants who have detectable HCV-RNA at Treatment Week 8 are assigned an additional 12 weeks of therapy, followed by 24 weeks of post treatment follow-up. Placebo replaces boceprevir for the remaining 12 weeks of therapy, and this switch will occur in a blinded fashion.
Boceprevir+PEG2b+RBV, x 44 Weeks	Participants in Arm 3 (experimental) received PEG2b + RBV (WBD) for 4 weeks followed by boceprevir + PEG2b + RBV (WBD) for 44 weeks with 24 weeks post-treatment follow-up.

Other Adverse Events

	Placebo+PEG2b+RBV, x 44 Weeks	Boceprevir+PEG2b+RBV, Response Guided Therapy	Boceprevir+PEG2b+RBV, x 44 Weeks
Total, other (not including serious) adverse events			
# participants affected / at risk	**77/80 (96.25%)**	**159/162 (98.15%)**	**160/161 (99.38%)**
Blood and lymphatic system disorders			
ANAEMIA † [1]			
# participants affected / at risk	**16/80 (20.00%)**	**70/162 (43.21%)**	**75/161 (46.58%)**
# events	**20**	**117**	**125**
LEUKOPENIA † [1]			
# participants affected / at risk	**1/80 (1.25%)**	**4/162 (2.47%)**	**11/161 (6.83%)**
# events	**3**	**12**	**18**
NEUTROPENIA † [1]			
# participants affected / at risk	**8/80 (10.00%)**	**23/162 (14.20%)**	**23/161 (14.29%)**
# events	**12**	**60**	**43**
THROMBOCYTOPENIA † [1]			
# participants affected / at risk	**0/80 (0.00%)**	**2/162 (1.23%)**	**10/161 (6.21%)**
# events	**0**	**4**	**12**
Gastrointestinal disorders			
ABDOMINAL PAIN † [1]			
# participants affected / at risk	**8/80 (10.00%)**	**4/162 (2.47%)**	**11/161 (6.83%)**
# events	**8**	**4**	**12**

ABDOMINAL PAIN UPPER † 1			
# participants affected / at risk	**2/80 (2.50%)**	**14/162 (8.64%)**	**12/161 (7.45%)**
# events	**2**	**23**	**16**
CONSTIPATION † 1			
# participants affected / at risk	**6/80 (7.50%)**	**15/162 (9.26%)**	**19/161 (11.80%)**
# events	**6**	**17**	**22**
DIARRHOEA † 1			
# participants affected / at risk	**13/80 (16.25%)**	**38/162 (23.46%)**	**40/161 (24.84%)**
# events	**21**	**59**	**59**
DRY MOUTH † 1			
# participants affected / at risk	**7/80 (8.75%)**	**21/162 (12.96%)**	**26/161 (16.15%)**
# events	**8**	**25**	**32**
DYSPEPSIA † 1			
# participants affected / at risk	**5/80 (6.25%)**	**11/162 (6.79%)**	**10/161 (6.21%)**
# events	**5**	**16**	**13**
GASTROOESOPHAGEAL REFLUX DISEASE † 1			
# participants affected / at risk	**0/80 (0.00%)**	**9/162 (5.56%)**	**9/161 (5.59%)**
# events	**0**	**9**	**9**
NAUSEA † 1			
# participants affected / at risk	**30/80 (37.50%)**	**72/162 (44.44%)**	**68/161 (42.24%)**
# events	**37**	**89**	**99**
STOMATITIS † 1			
# participants affected / at risk	**2/80 (2.50%)**	**10/162 (6.17%)**	**5/161 (3.11%)**
# events	**2**	**11**	**6**
VOMITING † 1			
# participants affected / at risk	**6/80 (7.50%)**	**23/162 (14.20%)**	**24/161 (14.91%)**
# events	**6**	**27**	**33**
General disorders			
ASTHENIA † 1			
# participants affected / at risk	**13/80 (16.25%)**	**30/162 (18.52%)**	**38/161 (23.60%)**
# events	**20**	**43**	**59**
CHILLS † 1			
# participants affected / at risk	**24/80 (30.00%)**	**56/162 (34.57%)**	**50/161 (31.06%)**
# events	**36**	**94**	**63**
FATIGUE † 1			
# participants affected / at risk	**40/80 (50.00%)**	**87/162 (53.70%)**	**92/161 (57.14%)**
# events	**59**	**137**	**115**
INFLUENZA LIKE ILLNESS † 1			
# participants affected / at risk	**20/80 (25.00%)**	**41/162 (25.31%)**	**38/161 (23.60%)**
# events	**20**	**51**	**44**
INJECTION SITE ERYTHEMA † 1			
# participants affected / at risk	**7/80 (8.75%)**	**22/162 (13.58%)**	**16/161 (9.94%)**
# events	**17**	**24**	**33**
INJECTION SITE REACTION † 1			

# participants affected / at risk	7/80 (8.75%)	9/162 (5.56%)	16/161 (9.94%)
# events	10	12	17
IRRITABILITY † 1			
# participants affected / at risk	10/80 (12.50%)	31/162 (19.14%)	36/161 (22.36%)
# events	13	38	41
PAIN † 1			
# participants affected / at risk	3/80 (3.75%)	11/162 (6.79%)	15/161 (9.32%)
# events	5	12	15
PYREXIA † 1			
# participants affected / at risk	20/80 (25.00%)	45/162 (27.78%)	48/161 (29.81%)
# events	32	58	67
Infections and infestations			
BRONCHITIS † 1			
# participants affected / at risk	6/80 (7.50%)	3/162 (1.85%)	6/161 (3.73%)
# events	6	5	7
NASOPHARYNGITIS † 1			
# participants affected / at risk	6/80 (7.50%)	5/162 (3.09%)	4/161 (2.48%)
# events	9	6	4
SINUSITIS † 1			
# participants affected / at risk	7/80 (8.75%)	7/162 (4.32%)	4/161 (2.48%)
# events	7	10	5
Investigations			
WEIGHT DECREASED † 1			
# participants affected / at risk	7/80 (8.75%)	21/162 (12.96%)	15/161 (9.32%)
# events	8	27	19
Metabolism and nutrition disorders			
DECREASED APPETITE † 1			
# participants affected / at risk	13/80 (16.25%)	37/162 (22.84%)	46/161 (28.57%)
# events	15	38	56
Musculoskeletal and connective tissue disorders			
ARTHRALGIA † 1			
# participants affected / at risk	13/80 (16.25%)	34/162 (20.99%)	39/161 (24.22%)
# events	15	36	53
BACK PAIN † 1			
# participants affected / at risk	5/80 (6.25%)	13/162 (8.02%)	14/161 (8.70%)
# events	7	16	15
MYALGIA † 1			
# participants affected / at risk	19/80 (23.75%)	46/162 (28.40%)	35/161 (21.74%)
# events	28	82	42
PAIN IN EXTREMITY † 1			
# participants affected / at risk	4/80 (5.00%)	3/162 (1.85%)	10/161 (6.21%)
# events	4	4	13
Nervous system disorders			
DISTURBANCE IN ATTENTION † 1			

# participants affected / at risk	6/80 (7.50%)	11/162 (6.79%)	12/161 (7.45%)
# events	7	11	17
DIZZINESS † 1			
# participants affected / at risk	8/80 (10.00%)	26/162 (16.05%)	26/161 (16.15%)
# events	8	29	36
DYSGEUSIA † 1			
# participants affected / at risk	9/80 (11.25%)	70/162 (43.21%)	72/161 (44.72%)
# events	9	79	86
HEADACHE † 1			
# participants affected / at risk	39/80 (48.75%)	69/162 (42.59%)	64/161 (39.75%)
# events	50	95	82
MEMORY IMPAIRMENT † 1			
# participants affected / at risk	4/80 (5.00%)	10/162 (6.17%)	5/161 (3.11%)
# events	5	10	5
Psychiatric disorders			
ANXIETY † 1			
# participants affected / at risk	6/80 (7.50%)	19/162 (11.73%)	20/161 (12.42%)
# events	7	25	23
DEPRESSION † 1			
# participants affected / at risk	12/80 (15.00%)	18/162 (11.11%)	28/161 (17.39%)
# events	12	21	39
INSOMNIA † 1			
# participants affected / at risk	19/80 (23.75%)	50/162 (30.86%)	47/161 (29.19%)
# events	33	65	62
Respiratory, thoracic and mediastinal disorders			
COUGH † 1			
# participants affected / at risk	14/80 (17.50%)	30/162 (18.52%)	40/161 (24.84%)
# events	20	36	59
DYSPNOEA † 1			
# participants affected / at risk	14/80 (17.50%)	29/162 (17.90%)	40/161 (24.84%)
# events	14	42	46
DYSPNOEA EXERTIONAL † 1			
# participants affected / at risk	4/80 (5.00%)	22/162 (13.58%)	14/161 (8.70%)
# events	4	23	14
EPISTAXIS † 1			
# participants affected / at risk	4/80 (5.00%)	10/162 (6.17%)	7/161 (4.35%)
# events	4	11	9
OROPHARYNGEAL PAIN † 1			
# participants affected / at risk	5/80 (6.25%)	7/162 (4.32%)	9/161 (5.59%)
# events	5	8	9
PRODUCTIVE COUGH † 1			
# participants affected / at risk	2/80 (2.50%)	4/162 (2.47%)	11/161 (6.83%)
# events	2	4	12
Skin and subcutaneous tissue			

disorders			
ALOPECIA † 1			
# participants affected / at risk	**13/80 (16.25%)**	**42/162 (25.93%)**	**29/161 (18.01%)**
# events	**14**	**44**	**30**
DRY SKIN † 1			
# participants affected / at risk	**7/80 (8.75%)**	**35/162 (21.60%)**	**37/161 (22.98%)**
# events	**11**	**40**	**45**
PRURITUS † 1			
# participants affected / at risk	**14/80 (17.50%)**	**31/162 (19.14%)**	**31/161 (19.25%)**
# events	**17**	**41**	**47**
RASH † 1			
# participants affected / at risk	**5/80 (6.25%)**	**27/162 (16.67%)**	**24/161 (14.91%)**
# events	**6**	**32**	**40**

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

Limitations and Caveats

Hide Limitations and Caveats

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

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:** Investigator may not publish/publicly present interim results without prior consent of Sponsor. Any materials that report results of the study must be sent to Sponsor 45 days prior to submission for publication/presentation. Sponsor has right to review and comment. In case of any disagreements concerning appropriateness of the materials, investigator and Sponsor must meet to make a good faith effort to discuss/resolve the issues or disagreement, prior to submission for publication/presentation.

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):

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

Bacon BR, Gordon SC, Lawitz E, Marcellin P, Vierling JM, Zeuzem S, Poordad F, Goodman ZD, Sings HL, Boparai N, Burroughs M, Brass CA, Albrecht JK, Esteban R; HCV RESPOND-2 Investigators. Boceprevir for previously treated chronic HCV genotype 1 infection. N Engl J Med. 2011 Mar 31;364(13):1207-17. doi: 10.1056/NEJMoa1009482.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00708500 History of Changes
Other Study ID Numbers:	P05101 2007-005151-42
Study First Received:	June 27, 2008
Results First Received:	May 13, 2011
Last Updated:	September 24, 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