Boceprevir Treatment in Participants With Chronic Hepatitis C Genotype 1 Deemed Nonresponders to Peginterferon/Ribavirin (P05514) (PROVIDE)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00910624

First received: May 28, 2009
Last updated: July 6, 2015
Last verified: July 2015
History of Changes

Purpose

This is a single-arm, multicenter study of boceprevir (BOC) in combination with peginterferon plus ribavirin (PEG/RBV) in adult chronic hepatitis C (CHC) genotype 1 participants who completed their per-protocol defined treatment and did not achieve sustained viral response (SVR) while in the PEG/RBV control arm(s) of an Schering-Plough Research Institute (SPRI) study of BOC combination therapy. Participants who are able to enroll in this study within 2 weeks after the last dose of PEG/RBV in previous protocol are to receive BOC+ PEG/RBV for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who are not able to enroll in this study within 2 weeks after the last dose of PEG/RBV in previous protocol are to receive PEG/RBV for 4 weeks followed by BOC+ PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.

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

Study Type: Interventional
Study Design: Endpoint Classification: Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Single-Arm Study to Provide Boceprevir Treatment in Subjects With Chronic Hepatitis C Genotype 1 Deemed Nonresponders to Peginterferon/Ribavirin in Previous Schering-Plough Boceprevir Studies

Resource links provided by NLM:

MedlinePlus related topics: Hepatitis Hepatitis A Hepatitis C

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

U.S. FDA Resources

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

Primary Outcome Measures:

- Percentage of Participants With Sustained Virologic Response at Follow-Up Week 24 (SVR24); [Time Frame: From start of 4-week PEG/RBV lead-in therapy or 44-week BOC/PR treatment through Follow-Up Week (FW) 24 (up to 68 weeks)] [Designated as safety issue: No]

  SVR24 was defined as undetectable Hepatitis C Virus ribonucleic acid (HCV-RNA) at Follow-up Week (FW) 24. SVR rates were evaluated by the prior interferon response (e.g., log drop from baseline at TW 4 or TW 12) in the previous studies.

- Percentage of Participants With Adverse Events (AEs) Leading to Dose Modification (DM) or Discontinuation (DC), Treatment-Related Serious AEs (SAEs), Neutrophil Count <0.75 × 10^9/L, or Hemoglobin (Hgb) <10 g/dL [Time Frame: From start of 4-week PEG/RBV lead-in therapy or 44-week BOC/PR treatment through FW 24 (up to 68 weeks)] [Designated as safety issue: Yes]

  AE= any untoward medical occurrence in a participant administered a pharmaceutical product/biologic (at any dose), whether or not considered related to the use of that product. Included the onset of new illness and the exacerbation of pre-existing conditions. Clinically significant laboratory abnormalities that required intervention/additional therapy, required a dose modification, or were associated with a clinical manifestation were considered AEs. SAE= any adverse drug or biologic or device experience occurring at any dose resulting in death, was life-threatening, was persistent or caused significant disability/incapacity, required in-patient hospitalization or prolonged hospitalization, or was a congenital anomaly or birth defect.

Secondary Outcome Measures:

- Percentage of Participants With Early Virologic Response (EVR) [Time Frame: From TW 1 to TW 12] [Designated as safety issue: No]

  EVR was defined as undetectable HCV-RNA at TW 12 of BOC + PEG/RBV. EVR rates were evaluated by the prior interferon response (e.g., log drop from baseline at TW 4 or TW 12) in the previous studies.

Enrollment:	168
Study Start Date:	June 2009
Study Completion Date:	December 2012
Primary Completion Date:	December 2012 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: BOC + PEG/RBV Participants who enrolled within 2 weeks after the last dose of PEG/RBV in previous protocol received boceprevir (BOC) + peginterferon/ribavirin (PEG/RBV) for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who did not enroll within 2 weeks after the last dose of PEG/RBV in previous protocol received PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.	Drug: Boceprevir Boceprevir, 200-mg capsules, 800 mg three times a day (TID) orally (PO) Other Name: SCH 503034 Biological: Peginterferon alfa-2b (SCH 54031) Peginterferon alfa-2b 1.5 µg/kg/week subcutaneously (SC) Other Name: PegIntron, PEG Drug: Ribavirin (SCH 18908) Ribavirin weight-based dosing (WBD) 600 mg/day to 1400 mg/day PO divided twice daily (BID). Other Name: Rebetol, RBV

Eligibility

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

Criteria

Inclusion Criteria:

- Participant must have been assigned to a PEG/RBV control arm in a previous SPRI study of BOC, must have completed treatment as per protocol, and have been compliant with all study treatment and scheduled procedures within the previous study.
- Participant must have received at least 12 weeks of treatment with PEG/RBV and must have discontinued treatment in the previous study due to the futility rule (as defined in the previous protocol), had virologic breakthrough, or relapse.
- Participant must have had detectable HCV-RNA upon completion of the previous study.
- Participant and participant partner(s) must each agree to use acceptable methods of contraception for at least 2 weeks prior to starting any study treatment and to continue until at least 6 months after the last doses of study drugs, or longer if dictated by local regulations.
- Participant must be willing to give written informed consent.

Exclusion Criteria:

- All participant exclusion criteria from the SPRI clinical study in which the participant participated prior to qualifying for this study will apply in this study, EXCEPT for the following:
  - Treatment with RBV within 90 days and any interferon-alpha within 1 month of the enrollment is not exclusionary in P05514.
  - Participation in any other SPRI clinical trial within 30 days of enrollment in this study is not exclusionary.
  - Use of growth factor at the entry of the study is allowed if it was prescribed in the previous study.
  - Laboratory criteria of thyroid-stimulating hormone (TSH) do not apply. Laboratory criteria of hemoglobin, neutrophils, and platelets do not apply, unless they met dose reduction/interruption/discontinuation criteria in the previous study.
  - Participants who develop moderate depression in the previous study and continue to be stable and well controlled are not excluded
- Participants who had the opportunity to receive boceprevir in the previous study.
- Participants requiring discontinuation, interruption, or dose reduction of RBV for more than 2 weeks in the previous study.
- Participants requiring discontinuation, interruption, or dose reduction of PEG to less than two-thirds of the assigned starting dose for more than 2 weeks in the previous study.
- Participants who experienced a life-threatening SAE considered at least possibly related to study drugs by the investigator or sponsor in the previous study.

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:

Vierling JM, Davis M, Flamm S, Gordon SC, Lawitz E, Yoshida EM, Galati J, Luketic V, McCone J, Jacobson I, Marcellin P, Muir AJ, Poordad F, Pedicone LD, Albrecht J, Brass C, Howe AY, Colvard LY, Helmond FA, Deng W, Treitel M, Wahl J, Bronowicki JP. Boceprevir for chronic HCV genotype 1 infection in patients with prior treatment failure to peginterferon/ribavirin, including prior null response. J Hepatol. 2014 Apr;60(4):748-56. doi: 10.1016/j.jhep.2013.12.013. Epub 2013 Dec 19.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00910624 History of Changes
Other Study ID Numbers: P05514
Study First Received: May 28, 2009
Results First Received: September 18, 2013
Last Updated: July 6, 2015

Health Authority: United States: Food and Drug Administration

Additional relevant MeSH terms:

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

ClinicalTrials.gov processed this record on May 08, 2016

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 Treatment in Participants With Chronic Hepatitis C Genotype 1 Deemed Nonresponders to Peginterferon/Ribavirin (P05514) (PROVIDE)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00910624

First received: May 28, 2009
Last updated: July 6, 2015
Last verified: July 2015
History of Changes

Results First Received: September 18, 2013

Study Type:	Interventional
Study Design:	Endpoint Classification: Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Hepatitis C, Chronic
Interventions:	Drug: Boceprevir Biological: Peginterferon alfa-2b (SCH 54031) Drug: Ribavirin (SCH 18908)

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
168 participants enrolled and received at least one dose of study medication. Participants were categorized by prior treatment response on the referring study: prior null response, prior partial response, prior relapse, or other.

Reporting Groups

	Description
BOC + PEG/RBV: Prior Null Responders	Participants who achieved “null” response (defined as <2-log10 decrease and detectable HCV RNA at Treatment Week (TW) 12 of PEG/RBV) after completing treatment on the PEG/RBV control arm on a previous SPRI study received BOC + PEG/RBV on the current study for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who were not able to enroll on the current study within 2 weeks after the last dose of PEG/RBV in previous protocol received PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.
BOC + PEG/RBV: Prior Partial Responders	Participants who achieved “partial” response (defined as ≥2-log10 decrease in HCV-RNA by TW 12 and detectable HCV-RNA at end of PEG/RBV) after completing treatment on the PEG/RBV control arm on a previous SPRI study received BOC + PEG/RBV on the current study for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who were not able to enroll on the current study within 2 weeks after the last dose of PEG/RBV in previous protocol received PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.
BOC + PEG/RBV: Prior Relapsers	Participants who achieved “prior relapse” (defined as undetectable HCV-RNA at end of treatment, and detectable HCV-RNA during follow-up period) after completing treatment on the PEG/RBV control arm on a previous SPRI study received BOC + PEG/RBV on the current study for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who were not able to enroll on the current study within 2 weeks after the last dose of PEG/RBV in previous protocol received PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.
BOC + PEG/RBV: Other	Participants who were characterized as “Other” (not in the categories of prior treatment failure as defined by this protocol), after completing treatment on the PEG/RBV control arm on a previous SPRI study, received BOC + PEG/RBV on the current study for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who were not able to enroll on the current study within 2 weeks after the last dose of PEG/RBV in previous protocol received PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.

Participant Flow for 2 periods

Period 1: Treatment Phase

	BOC + PEG/RBV: Prior Null Responders	BOC + PEG/RBV: Prior Partial Responders	BOC + PEG/RBV: Prior Relapsers	BOC + PEG/RBV: Other
STARTED	52	85	29	2
COMPLETED	22	64	20	2
NOT COMPLETED	30	21	9	0
Adverse Event	2	6	6	0
Treatment Failure	23	10	0	0
Lost to Follow-up	0	0	1	0
Reasons Unrelated To Assigned Treatment	3	3	1	0
Withdrawal by Subject	2	1	0	0
Non-Compliance With Protocol	0	1	1	0

Period 2: Follow-Up Phase

	BOC + PEG/RBV: Prior Null Responders	BOC + PEG/RBV: Prior Partial Responders	BOC + PEG/RBV: Prior Relapsers	BOC + PEG/RBV: Other

STARTED	**48**	**80**	**29**	**2**
COMPLETED	**42**	**76**	**25**	**2**
NOT COMPLETED	**6**	**4**	**4**	**0**
Adverse Event	**0**	**0**	**1**	**0**
Lost to Follow-up	**3**	**1**	**2**	**0**
Reasons Unrelated To Assigned Treatment	**1**	**2**	**0**	**0**
Withdrawal by Subject	**1**	**0**	**0**	**0**
Withdrew Due To Retreatment Opportunity	**1**	**0**	**0**	**0**
Administrative	**0**	**1**	**1**	**0**

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
BOC + PEG/RBV: Prior Null Responders	Participants who achieved “null” response (defined as <2-log10 decrease and detectable HCV RNA at TW 12 of PEG/RBV) after completing treatment on the PEG/RBV control arm on a previous SPRI study received BOC + PEG/RBV on the current study for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who were not able to enroll on the current study within 2 weeks after the last dose of PEG/RBV in previous protocol received PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.
BOC + PEG/RBV: Prior Partial Responders	Participants who achieved “partial” response (defined as ≥2-log10 decrease in HCV-RNA by TW 12 and detectable HCV-RNA at end of PEG/RBV) after completing treatment on the PEG/RBV control arm on a previous SPRI study received BOC + PEG/RBV on the current study for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who were not able to enroll on the current study within 2 weeks after the last dose of PEG/RBV in previous protocol received PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.
BOC + PEG/RBV: Prior Relapsers	Participants who achieved “prior relapse” (defined as undetectable HCV-RNA at end of treatment, and detectable HCV-RNA during follow-up period) after completing treatment on the PEG/RBV control arm on a previous SPRI study received BOC + PEG/RBV on the current study for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who were not able to enroll on the current study within 2 weeks after the last dose of PEG/RBV in previous protocol received PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.
BOC + PEG/RBV: Other	Participants who were characterized as “Other” (not in the categories of prior treatment failure as defined by this protocol), after completing treatment on the PEG/RBV control arm on a previous SPRI study, received BOC + PEG/RBV on the current study for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who were not able to enroll on the current study within 2 weeks after the last dose of PEG/RBV in previous protocol received PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.
Total	Total of all reporting groups

Baseline Measures

	BOC + PEG/RBV: Prior Null Responders	BOC + PEG/RBV: Prior Partial Responders	BOC + PEG/RBV: Prior Relapsers	BOC + PEG/RBV: Other	Total
Number of Participants [units: participants]	52	85	29	2	168
Age [units: years] Mean (Standard Deviation)	51.3 (7.7)	52.6 (8.4)	53.6 (6.4)	52.0 (1.4)	52.3 (7.8)
Gender [units: participants]					
Female	19	25	10	1	55
Male	33	60	19	1	113

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants With Sustained Virologic Response at Follow-Up Week 24 (SVR24); [Time Frame: From start of 4-week PEG/RBV lead-in therapy or 44-week BOC/PR treatment through Follow-Up Week (FW) 24 (up to 68 weeks)]

Measure Type	Primary
Measure Title	Percentage of Participants With Sustained Virologic Response at Follow-Up Week 24 (SVR24);
Measure Description	SVR24 was defined as undetectable Hepatitis C Virus ribonucleic acid (HCV-RNA) at Follow-up Week (FW) 24. SVR rates were evaluated by the prior interferon response (e.g., log drop from baseline at TW 4 or TW 12) in the previous studies.
Time Frame	From start of 4-week PEG/RBV lead-in therapy or 44-week BOC/PR treatment through Follow-Up Week (FW) 24 (up to 68 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All BOC-Treated Participants: All enrolled participants who received at least 1 dose of BOC. Data for 2 "Other" participants were included in the calculations for "BOC + PEG/RBV: All " (n=164). 4 discontinued during the 4-week PEG/RBV lead-in and did not receive BOC and thus were excluded from analysis.

Reporting Groups

	Description
BOC + PEG/RBV: Prior Null Responders	Participants who achieved “null” response (defined as <2-log10 decrease and detectable HCV RNA at TW 12 of PEG/RBV) after completing treatment on the PEG/RBV control arm on a previous SPRI study received BOC + PEG/RBV on the current study for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who were not able to enroll on the current study within 2 weeks after the last dose of PEG/RBV in previous protocol received PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.
BOC + PEG/RBV: Prior Partial Responders	Participants who achieved “partial” response (defined as ≥2-log10 decrease in HCV-RNA by TW

	12 and detectable HCV-RNA at end of PEG/RBV) after completing treatment on the PEG/RBV control arm on a previous SPRI study received BOC + PEG/RBV on the current study for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who were not able to enroll on the current study within 2 weeks after the last dose of PEG/RBV in previous protocol received PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.
BOC + PEG/RBV: Prior Relapsers	Participants who achieved “prior relapse” (defined as undetectable HCV-RNA at end of treatment, and detectable HCV-RNA during follow-up period) after completing treatment on the PEG/RBV control arm on a previous SPRI study received BOC + PEG/RBV on the current study for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who were not able to enroll on the current study within 2 weeks after the last dose of PEG/RBV in previous protocol received PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.
BOC + PEG/RBV: All	Participants who enrolled within 2 weeks after the last dose of PEG/RBV in previous SPRI study received boceprevir (BOC) + peginterferon/ribavirin (PEG/RBV) for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who did not enroll within 2 weeks after the last dose of PEG/RBV in previous protocol received PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.

Measured Values

	BOC + PEG/RBV: Prior Null Responders	BOC + PEG/RBV: Prior Partial Responders	BOC + PEG/RBV: Prior Relapsers	BOC + PEG/RBV: All
Number of Participants Analyzed [units: participants]	**49**	**85**	**28**	**164**
Percentage of Participants With Sustained Virologic Response at Follow-Up Week 24 (SVR24); [units: percentage of participants]	**41**	**67**	**96**	**65**

No statistical analysis provided for Percentage of Participants With Sustained Virologic Response at Follow-Up Week 24 (SVR24);

2. Primary: Percentage of Participants With Adverse Events (AEs) Leading to Dose Modification (DM) or Discontinuation (DC), Treatment-Related Serious AEs (SAEs), Neutrophil Count <0.75 × 10^9/L, or Hemoglobin (Hgb) <10 g/dL [Time Frame: From start of 4-week PEG/RBV lead-in therapy or 44-week BOC/PR treatment through FW 24 (up to 68 weeks)]

Measure Type	Primary
Measure Title	Percentage of Participants With Adverse Events (AEs) Leading to Dose Modification (DM) or Discontinuation (DC), Treatment-Related Serious AEs (SAEs), Neutrophil Count <0.75 × 10^9/L, or Hemoglobin (Hgb) <10 g/dL
Measure Description	AE= any untoward medical occurrence in a participant administered a pharmaceutical product/biologic (at any dose), whether or not considered related to the use of that product. Included the onset of new illness and the exacerbation of pre-existing conditions. Clinically significant laboratory abnormalities that required intervention/additional therapy, required a dose modification, or were associated with a clinical manifestation were considered AEs. SAE= any adverse drug or biologic or device experience occurring at any dose resulting in death, was life-threatening, was persistent or caused significant disability/incapacity, required in-patient hospitalization or prolonged hospitalization, or was a congenital anomaly or birth defect.
Time Frame	From start of 4-week PEG/RBV lead-in therapy or 44-week BOC/PR treatment through FW 24 (up to 68 weeks)
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

All Treated Participants: All enrolled participants who received at least one dose of treatment.

Reporting Groups

	Description
All Treated Participants	Participants who enrolled within 2 weeks after the last dose of PEG/RBV in previous SPRI study received boceprevir (BOC) + peginterferon/ribavirin (PEG/RBV) for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who did not enroll within 2 weeks after the last dose of PEG/RBV in previous protocol received PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.

Measured Values

	All Treated Participants
Number of Participants Analyzed [units: participants]	**168**
Percentage of Participants With Adverse Events (AEs) Leading to Dose Modification (DM) or Discontinuation (DC), Treatment-Related Serious AEs (SAEs), Neutrophil Count <0.75 × 10^9/L, or Hemoglobin (Hgb) <10 g/dL [units: percentage of participants]	
AEs Leading to DC	**8**
AEs Leading to DM	**35**
All Treatment-Related SAEs	**7**
SAEs Related to BOC+PEG or BOC+P/R	**4**
Neutrophil Count <0.75 × 10^9/L	**25**
Hgb <10 g/dL	**53**

No statistical analysis provided for Percentage of Participants With Adverse Events (AEs) Leading to Dose Modification (DM) or Discontinuation (DC), Treatment-Related Serious AEs (SAEs), Neutrophil Count <0.75 × 10^9/L, or Hemoglobin (Hgb) <10 g/dL

3. Secondary: Percentage of Participants With Early Virologic Response (EVR) [Time Frame: From TW 1 to TW 12]

Measure Type	Secondary
Measure Title	Percentage of Participants With Early Virologic Response (EVR)
Measure Description	EVR was defined as undetectable HCV-RNA at TW 12 of BOC + PEG/RBV. EVR rates were evaluated by the prior interferon response (e.g., log drop from baseline at TW 4 or TW 12) in the previous studies.
Time Frame	From TW 1 to TW 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 BOC-Treated Participants: All enrolled participants who received at least 1 dose of BOC. Data for 2 "Other" participants were included in the calculations for "BOC + PEG/RBV: All " (n=164). 4 discontinued during the 4-week PEG/RBV lead-in and did not receive BOC and thus were excluded from analysis.

Reporting Groups

	Description

BOC + PEG/RBV: Prior Null Responders	Participants who achieved “null” response (defined as <2-log10 decrease and detectable HCV RNA at TW 12 of PEG/RBV) after completing treatment on the PEG/RBV control arm on a previous SPRI study received BOC + PEG/RBV on the current study for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who were not able to enroll on the current study within 2 weeks after the last dose of PEG/RBV in previous protocol received PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.
BOC + PEG/RBV: Prior Partial Responders	Participants who achieved “partial” response (defined as ≥2-log10 decrease in HCV-RNA by TW 12 and detectable HCV-RNA at end of PEG/RBV) after completing treatment on the PEG/RBV control arm on a previous SPRI study received BOC + PEG/RBV on the current study for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who were not able to enroll on the current study within 2 weeks after the last dose of PEG/RBV in previous protocol received PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.
BOC + PEG/RBV: Prior Relapsers	Participants who achieved “prior relapse” (defined as undetectable HCV-RNA at end of treatment, and detectable HCV-RNA during follow-up period) after completing treatment on the PEG/RBV control arm on a previous SPRI study received BOC + PEG/RBV on the current study for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who were not able to enroll on the current study within 2 weeks after the last dose of PEG/RBV in previous protocol received PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.
BOC + PEG/RBV: All	Participants who enrolled within 2 weeks after the last dose of PEG/RBV in previous SPRI study received boceprevir (BOC) + peginterferon/ribavirin (PEG/RBV) for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who did not enroll within 2 weeks after the last dose of PEG/RBV in previous protocol received PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.

Measured Values

	BOC + PEG/RBV: Prior Null Responders	BOC + PEG/RBV: Prior Partial Responders	BOC + PEG/RBV: Prior Relapsers	BOC + PEG/RBV: All
Number of Participants Analyzed [units: participants]	**49**	**85**	**28**	**164**
Percentage of Participants With Early Virologic Response (EVR) [units: percentage of participants]	**49**	**76**	**100**	**73**

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

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	From start of 4-week PEG/RBV lead-in therapy or 44-week BOC/PR treatment through FW 24 (up to 68 weeks)
Additional Description	Only treatment-emergent AEs occurring on the present study (NCT00910624) and AEs occurring during the follow-up period of the present study are reported.

Reporting Groups

	Description
All Treated Participants	Participants who enrolled within 2 weeks after the last dose of PEG/RBV in previous SPRI study received boceprevir (BOC) + peginterferon/ribavirin (PEG/RBV) for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who did not enroll within 2 weeks after the last dose of PEG/RBV in previous protocol received

	PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.

Serious Adverse Events

	All Treated Participants
Total, serious adverse events	
# participants affected / at risk	**18/168 (10.71%)**
Gastrointestinal disorders	
Abdominal pain [1]	
# participants affected / at risk	**1/168 (0.60%)**
# events	**1**
Diarrhoea [1]	
# participants affected / at risk	**2/168 (1.19%)**
# events	**2**
General disorders	
Chest pain [1]	
# participants affected / at risk	**2/168 (1.19%)**
# events	**2**
Oedema peripheral [1]	
# participants affected / at risk	**1/168 (0.60%)**
# events	**1**
Hepatobiliary disorders	
Hepatic cirrhosis [1]	
# participants affected / at risk	**1/168 (0.60%)**
# events	**1**
Immune system disorders	
Sarcoidosis [1]	
# participants affected / at risk	**1/168 (0.60%)**
# events	**1**
Infections and infestations	
Appendicitis [1]	
# participants affected / at risk	**1/168 (0.60%)**
# events	**1**
Cellulitis [1]	
# participants affected / at risk	**1/168 (0.60%)**
# events	**1**
Injection site abscess [1]	
# participants affected / at risk	**1/168 (0.60%)**
# events	**1**
Lobar pneumonia [1]	
# participants affected / at risk	**1/168 (0.60%)**
# events	**1**
Staphylococcal infection [1]	
# participants affected / at risk	**1/168 (0.60%)**

# events	1
Injury, poisoning and procedural complications	
Joint injury [1]	
# participants affected / at risk	1/168 (0.60%)
# events	1
Metabolism and nutrition disorders	
Dehydration [1]	
# participants affected / at risk	1/168 (0.60%)
# events	1
Hyponatraemia [1]	
# participants affected / at risk	1/168 (0.60%)
# events	1
Musculoskeletal and connective tissue disorders	
Muscular weakness [1]	
# participants affected / at risk	1/168 (0.60%)
# events	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
Salivary gland neoplasm [1]	
# participants affected / at risk	1/168 (0.60%)
# events	1
Psychiatric disorders	
Acute psychosis [1]	
# participants affected / at risk	1/168 (0.60%)
# events	1
Mood swings [1]	
# participants affected / at risk	1/168 (0.60%)
# events	1
Vascular disorders	
Arterial occlusive disease [1]	
# participants affected / at risk	1/168 (0.60%)
# events	1
Femoral artery occlusion [1]	
# participants affected / at risk	1/168 (0.60%)
# events	1

1 Term from vocabulary, MedDRA 15.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	From start of 4-week PEG/RBV lead-in therapy or 44-week BOC/PR treatment through FW 24 (up to 68 weeks)
Additional Description	Only treatment-emergent AEs occurring on the present study (NCT00910624) and AEs occurring during the follow-up period of the present study are reported.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
All Treated Participants	Participants who enrolled within 2 weeks after the last dose of PEG/RBV in previous SPRI study received boceprevir (BOC) + peginterferon/ribavirin (PEG/RBV) for up to 44 weeks followed by 24 weeks post-treatment follow-up. Participants who did not enroll within 2 weeks after the last dose of PEG/RBV in previous protocol received PEG/RBV for 4 weeks followed by BOC + PEG/RBV for up to 44 weeks, with 24 weeks post-treatment follow-up.

Other Adverse Events

	All Treated Participants
Total, other (not including serious) adverse events	
# participants affected / at risk	**161/168 (95.83%)**
Blood and lymphatic system disorders	
Anaemia [1]	
# participants affected / at risk	**83/168 (49.40%)**
# events	**141**
Leukopenia [1]	
# participants affected / at risk	**15/168 (8.93%)**
# events	**19**
Neutropenia [1]	
# participants affected / at risk	**38/168 (22.62%)**
# events	**53**
Thrombocytopenia [1]	
# participants affected / at risk	**10/168 (5.95%)**
# events	**15**
Gastrointestinal disorders	
Abdominal pain [1]	
# participants affected / at risk	**12/168 (7.14%)**
# events	**16**
Abdominal pain upper [1]	
# participants affected / at risk	**10/168 (5.95%)**
# events	**10**
Constipation [1]	
# participants affected / at risk	**9/168 (5.36%)**
# events	**11**
Diarrhoea [1]	
# participants affected / at risk	**37/168 (22.02%)**
# events	**49**
Dry mouth [1]	
# participants affected / at risk	**10/168 (5.95%)**
# events	**11**

Dysgeusia [1]	
# participants affected / at risk	**59/168 (35.12%)**
# events	**64**
Dyspepsia [1]	
# participants affected / at risk	**12/168 (7.14%)**
# events	**12**
Gastrooesophageal reflux disease [1]	
# participants affected / at risk	**10/168 (5.95%)**
# events	**13**
Nausea [1]	
# participants affected / at risk	**52/168 (30.95%)**
# events	**59**
Vomiting [1]	
# participants affected / at risk	**14/168 (8.33%)**
# events	**16**
General disorders	
Asthenia [1]	
# participants affected / at risk	**23/168 (13.69%)**
# events	**27**
Chills [1]	
# participants affected / at risk	**27/168 (16.07%)**
# events	**28**
Fatigue [1]	
# participants affected / at risk	**81/168 (48.21%)**
# events	**104**
Influenza like illness [1]	
# participants affected / at risk	**35/168 (20.83%)**
# events	**37**
Injection site reaction [1]	
# participants affected / at risk	**16/168 (9.52%)**
# events	**16**
Irritability [1]	
# participants affected / at risk	**25/168 (14.88%)**
# events	**32**
Pain [1]	
# participants affected / at risk	**10/168 (5.95%)**
# events	**12**
Pyrexia [1]	
# participants affected / at risk	**22/168 (13.10%)**
# events	**27**
Investigations	
Weight decreased [1]	
# participants affected / at risk	**15/168 (8.93%)**
# events	**18**
Metabolism and nutrition disorders	

Decreased appetite [1]	
# participants affected / at risk	**35/168 (20.83%)**
# events	**40**
Musculoskeletal and connective tissue disorders	
Arthralgia [1]	
# participants affected / at risk	**16/168 (9.52%)**
# events	**16**
Back pain [1]	
# participants affected / at risk	**9/168 (5.36%)**
# events	**15**
Myalgia [1]	
# participants affected / at risk	**16/168 (9.52%)**
# events	**18**
Nervous system disorders	
Disturbance in attention [1]	
# participants affected / at risk	**11/168 (6.55%)**
# events	**11**
Dizziness [1]	
# participants affected / at risk	**27/168 (16.07%)**
# events	**32**
Headache [1]	
# participants affected / at risk	**45/168 (26.79%)**
# events	**50**
Psychiatric disorders	
Depression [1]	
# participants affected / at risk	**22/168 (13.10%)**
# events	**25**
Insomnia [1]	
# participants affected / at risk	**40/168 (23.81%)**
# events	**52**
Respiratory, thoracic and mediastinal disorders	
Cough [1]	
# participants affected / at risk	**25/168 (14.88%)**
# events	**30**
Dyspnoea [1]	
# participants affected / at risk	**31/168 (18.45%)**
# events	**35**
Skin and subcutaneous tissue disorders	
Alopecia [1]	
# participants affected / at risk	**26/168 (15.48%)**
# events	**29**
Dry skin [1]	
# participants affected / at risk	**28/168 (16.67%)**
# events	**31**

Pruritus [1]	
# participants affected / at risk	**25/168 (14.88%)**
# events	**25**
Rash [1]	
# participants affected / at risk	**24/168 (14.29%)**
# events	**29**

1 Term from vocabulary, MedDRA 15.1

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 agrees not to publish or publicly present any interim results of the study without the prior written consent of the sponsor, and further agrees to provide to the sponsor 45 days prior to submission for publication or presentation, review copies of abstracts or manuscripts for publication that report any results of the study.

Results Point of Contact:

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

Publications of Results:

Vierling JM, Davis M, Flamm S, Gordon SC, Lawitz E, Yoshida EM, Galati J, Luketic V, McCone J, Jacobson I, Marcellin P, Muir AJ, Poordad F, Pedicone LD, Albrecht J, Brass C, Howe AY, Colvard LY, Helmond FA, Deng W, Treitel M, Wahl J, Bronowicki JP. Boceprevir for chronic HCV genotype 1 infection in patients with prior treatment failure to peginterferon/ribavirin, including prior null response. J Hepatol. 2014 Apr;60(4):748-56. doi: 10.1016/j.jhep.2013.12.013. Epub 2013 Dec 19.

Responsible Party: Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:	NCT00910624 History of Changes
Other Study ID Numbers:	P05514
Study First Received:	May 28, 2009
Results First Received:	September 18, 2013
Last Updated:	July 6, 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