Boceprevir in Combination With Peginterferon Alfa-2a and Ribavirin in Participants With Chronic Hepatitis C Genotype 1 Who Failed Prior Treatment With Peginterferon/Ribavirin (Study P05685AM2)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00845065

First received: February 13, 2009
Last updated: September 24, 2015
Last verified: September 2015
History of Changes

Purpose

Based on previous experience with peginterferon alfa-2b/ribavirin in combination with boceprevir, the combination with peginterferon alfa-2a/ribavirin and boceprevir is expected to be safe and well tolerated. Given the wide utilization of both peginterferons and the clear benefit of the addition of boceprevir to peginterferon alfa-2b/ribavirin, it is important to demonstrate the safety and efficacy of boceprevir in combination with peginterferon alfa-2a/ribavirin.

Condition	Intervention	Phase
Hepatitis C, Chronic	Drug: Boceprevir Other: Placebo Biological: Peginterferon alfa-2a Drug: Ribavirin	Phase 3

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

Official Title: A Phase 3 Safety and Efficacy Study of Boceprevir in Combination With Peginterferon Alfa-2a and Ribavirin 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: Ribavirin Peginterferon Alfa-2a Boceprevir

U.S. FDA Resources

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

Primary Outcome Measures:

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

  SVR rate was the percentage of participants treated with at least one dose of study medication (PEG2a, Ribavirin, or Boceprevir/Placebo) who had achieved SVR. SVR was defined as undetectable Hepatitis C Virus-Ribonucleic Acid (HCV RNA).

Secondary Outcome Measures:

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

  SVR rate was the percentage of participants treated with at least one dose of study medication (Boceprevir/PEG2a/Ribavirin or PEG2a/Ribavirin). Participants who discontinued study drugs during the 4-week PEG2a/Ribavirin lead-in period were not included in the mITT population.

- Percentage of Participants With Early Virologic Response (EVR) Who Achieved SVR [Time Frame: Day 1 to Treatment Week 12] [Designated as safety issue: No]

  EVR was defined as the time to the first undectectable HCV-RNA result at Treatment Week (TW) 2, 4, 8, or 12. Participants with a detectable, but not quantifiable HCV-RNA result at TW 12 may have undergone retesting. Participants with a detectable result on retesting were to be discontinued per the 12-week futility rule. Participants with an undetectable result on retesting were allowed to continue on treatment, and the detectable but not quantifiable result was to be considered a false positive.

- Number of Participants With Undetectable HCV-RNA at Follow-up Week 12 [Time Frame: Follow-up Week 12] [Designated as safety issue: No]
- Mean Log Change From Baseline to TW 4 in Viral Load by Visit [Time Frame: From Baseline to TW 4] [Designated as safety issue: No]

  HCV-RNA levels were quantified using the Roche Cobas Taqman 1.0 assay; lower limit of detection of 15 international units [IU]/mL. Changes in HCV-RNA IU/ml were expressed on a log10 scale.

Enrollment:	202
Study Start Date:	February 2009
Study Completion Date:	October 2010
Primary Completion Date:	October 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Placebo Comparator: Arm 1 (Control Arm) Peginterferon alfa-2a (180 µg/week subcutaneously [SC]) plus ribavirin (1000 to 1200 mg/day orally [PO]) for 4 weeks followed by placebo (800 mg three times a day [TID] PO, using placebo matching SCH 503034 200-mg capsules) + peginterferon alfa-2a 180 µg/week SC plus ribavirin 1000 to 1200 mg/day PO divided twice daily (BID) for 48 weeks with 24 weeks post-treatment follow-up.	Other: Placebo 800 mg, using placebo matching SCH 503034 200-mg capsules, three times a day (TID) orally (PO) for 48 weeks Biological: Peginterferon alfa-2a Peginterferon alfa-2a, pre-filled syringes, given 180 µg/week subcutaneously (SC) for 48 weeks Other Name: Pegasys® Drug: Ribavirin Ribavirin 200-mg capsules, weight-based dosing • <75 kg, 1000 mg/day orally (PO), divided twice daily (BID) • >=75 kg, 1200 mg/day

	PO, divided BID for 48 weeks Other Name: SCH 18908
Experimental: Arm 2 (Boceprevir Arm) Peginterferon alfa-2a (180 µg/week subcutaneously [SC]) plus ribavirin (1000 to 1200 mg/day orally [PO]) for 4 weeks followed by boceprevir (800 mg three times a day [TID] PO, using SCH 503034 200-mg capsules) + peginterferon alfa-2a 180 µg/week SC plus ribavirin 1000 to 1200 mg/day PO divided twice daily (BID) for 48 weeks with 24 weeks post-treatment follow-up.	Drug: Boceprevir 800 mg, using SCH 503034 200-mg capsules, three times a day (TID) orally (PO) for 48 weeks Other Name: SCH 503034 Biological: Peginterferon alfa-2a Peginterferon alfa-2a, pre-filled syringes, given 180 µg/week subcutaneously (SC) for 48 weeks Other Name: Pegasys® Drug: Ribavirin Ribavirin 200-mg capsules, weight-based dosing • <75 kg, 1000 mg/day orally (PO), divided twice daily (BID) • >=75 kg, 1200 mg/day PO, divided BID for 48 weeks Other Name: SCH 18908

Eligibility

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

Criteria

Inclusion Criteria:

- Subjects must have a qualifying regimen defined as peginterferon alfa-2a/ribavirin or peginterferon alfa-2b/ribavirin for a minimum of 12 weeks.
- During the qualifying regimen, subjects must have either:
  - A documented undetectable Hepatitis C Virus-Ribonucleic Acid (HCV-RNA) within 30 days of the end-of-treatment and a subsequent detectable HCV-RNA during follow-up OR
  - A documented decline in HCV-RNA by >=2 log10 after 12 weeks of treatment.
- Subject must have previously documented chronic hepatitis C genotype 1 infection.
- Subject must have a liver biopsy with histology consistent with chronic hepatitis C infection and no other etiology.
- Subjects with bridging fibrosis or cirrhosis must have an ultrasound within 6 months with no findings suspicious for hepatocellular carcinoma (HCC).
- Subject must be >=18 years of age.
- Subject must weigh between 40 kg and 125 kg.
- Subject and subject's partner(s) must each agree to use acceptable methods of contraception.
- Subjects must be willing to give written informed consent.

Exclusion Criteria:

Subject will be excluded from entry if ANY of the criteria listed below are

met:

- Subjects known to be coinfected with the human immunodeficiency virus (HIV) or hepatitis B virus (hepatitis B surface antigen [HBsAg]

positive) and/or demonstrating signs and symptoms consistent with co-infection.

- Subjects who required discontinuation of previous interferon or ribavirin regimen for an adverse event considered by the investigator to be possibly or probably related to ribavirin and/or interferon.
- Treatment with ribavirin within 90 days and any interferon alfa within 1 month of Screening.
- Treatment for hepatitis C with any investigational medication. Prior treatment with herbal remedies with known hepatotoxicity is exclusionary.
- Treatment with any investigational drug within 30 days of the randomization visit in this study.
- Participation in any other clinical trial within 30 days of randomization or intention to participate in another clinical trial during participation in this study.
- Evidence of decompensated liver disease.
- Diabetic and/or hypertensive subjects with clinically significant ocular examination findings.
- Pre-existing psychiatric condition(s).
- Clinical diagnosis of substance abuse.
- Any known pre-existing medical condition that could interfere with the subject'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).
- Subjects who are pregnant or nursing. Subjects who intend to become pregnant during the study period. Male subjects with partners who are or who intend to become pregnant during the study period.
- Any other condition which, in the opinion of a physician, would make the subject unsuitable for enrollment or could interfere with the subject participating in and completing the study.
- Subjects who are part of the site personnel directly involved with this study.
- Subjects who are family members of the investigational study staff.
- Subjects who had a life-threatening serious adverse event (SAE) during the screening period.
- Subjects with a history of pancreatitis, except for one episode clearly secondary to gallstone.

Laboratory Exclusion Criteria:

- Hematologic, biochemical, and serologic criteria (growth factors may not be used to achieve study entry requirements):
  - Hemoglobin (Hgb) <12 g/dL for females and <13 g/dL for males
  - Neutrophils <1500/mm3 (blacks: <1200/mm3)
  - Platelets <100,000/mm3
  - Direct bilirubin >1.5 x upper limit of normal (ULN) of the laboratory reference range. Total bilirubin >1.6 mg/dL unless the subject has a history of Gilbert's disease. If Gilbert's disease is the proposed etiology, this must be documented in the subject's chart.
- Serum albumin < lower limit of normal (LLN) of laboratory reference range.
- Thyroid-stimulating hormone (TSH) >1.2 x ULN or <0.8 x LLN of laboratory reference range.
- Serum creatinine >ULN of the laboratory reference range.
- Serum glucose:
  - For subjects not previously diagnosed with diabetes mellitus:
    - >=140 mg/dL (nonfasting) unless hemoglobin A1c subtype (HbA1c) <=7% OR
    - >=100 mg/dL (fasting) unless HbA1c <=7%.
  - For subjects previously diagnosed with diabetes mellitus: HbA1c >8.5%.
- Prothrombin time/partial thromboplastin time (PT/PTT) values >10% above laboratory reference range.
- Anti-nuclear antibodies (ANA) >1:320.
- Alpha fetoprotein (AFP):
  - AFP >100 ng/mL OR
  - AFP 50 to 100 ng/mL requires a liver ultrasound and subjects with findings suspicious for HCC are excluded.

Contacts and Locations

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

No Contacts or Locations Provided

More Information

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

Flamm SL, Lawitz E, Jacobson I, Bourlière M, Hezode C, Vierling JM, Bacon BR, Niederau C, Sherman M, Goteti V, Sings HL, Barnard RO, Howe JA, Pedicone LD, Burroughs MH, Brass CA, Albrecht JK, Poordad F. Boceprevir with peginterferon alfa-2a-ribavirin is effective for previously treated chronic hepatitis C genotype 1 infection. Clin Gastroenterol Hepatol. 2013 Jan;11(1):81-87.e4; quiz e5. doi: 10.1016/j.cgh.2012.10.006. Epub 2012 Oct 10.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00845065 History of Changes
Other Study ID Numbers:	P05685
Study First Received:	February 13, 2009
Results First Received:	October 10, 2011
Last Updated:	September 24, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Hepatitis	Virus Diseases
Hepatitis A	Interferon-alpha
Hepatitis C	Peginterferon alfa-2a
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

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First received: February 13, 2009
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History of Changes

Results First Received: October 10, 2011

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

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
A total of 202 participants were randomized but 1 participant was not treated.

Pre-Assignment Details

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

Reporting Groups

	Description
PEG2a/Ribavirin	Peginterferon alfa-2a (PEG2a) (180 µg/week subcutaneously [SC]) plus ribavirin (1000 to 1200 mg/day orally [PO]) for 4 weeks followed by placebo (800 mg three times a day [TID] PO, using placebo matching SCH 503034 200-mg capsules) + PEG2a 180 µg/week SC plus ribavirin 1000 to 1200 mg/day PO divided twice daily (BID) for 48 weeks with 24 weeks post-treatment follow-up.
Boceprevir/PEG2a/Ribavirin	PEG2a (180 µg/week SC) plus ribavirin (1000 to 1200 mg/day PO) for 4 weeks followed by boceprevir (800 mg TID PO, using SCH 503034 200-mg capsules) + PEG2a 180 µg/week SC plus ribavirin 1000 to 1200 mg/day PO divided BID for 48 weeks with 24 weeks post-treatment follow-up.

Participant Flow: Overall Study

	PEG2a/Ribavirin	Boceprevir/PEG2a/Ribavirin
STARTED	**67**	**134**
COMPLETED	**20**	**79**
NOT COMPLETED	**47**	**55**
Adverse Event	**3**	**23**
Lack of Efficacy	**43**	**21**
Non-Medical Reasons	**1**	**11**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

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

Reporting Groups

	Description
PEG2a/Ribavirin	Peginterferon alfa-2a (PEG2a) (180 µg/week subcutaneously [SC]) plus ribavirin (1000 to 1200 mg/day orally [PO]) for 4 weeks followed by placebo (800 mg three times a day [TID] PO, using placebo matching SCH 503034 200-mg capsules) + PEG2a 180 µg/week SC plus ribavirin 1000 to 1200 mg/day PO divided twice daily (BID) for 48 weeks with 24 weeks post-treatment follow-up.
Boceprevir/PEG2a/Ribavirin	PEG2a (180 µg/week SC) plus ribavirin (1000 to 1200 mg/day PO) for 4 weeks followed by boceprevir (800 mg TID PO, using SCH 503034 200-mg capsules) + PEG2a 180 µg/week SC plus ribavirin 1000 to 1200 mg/day PO divided BID for 48 weeks with 24 weeks post-treatment follow-up.
Total	Total of all reporting groups

Baseline Measures

	PEG2a/Ribavirin	Boceprevir/PEG2a/Ribavirin	Total
Number of Participants [units: participants]	**67**	**134**	**201**
Age			

[units: years] Mean (Standard Deviation)	53.5 (6.8)	52.0 (7.2)	52.5 (7.1)
Gender [units: participants]			
Female	24	37	61
Male	43	97	140

Outcome Measures

Hide All Outcome Measures

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

Measure Type	Primary
Measure Title	Sustained Virologic Response (SVR) Rate in Full Analysis Set (FAS) Population.
Measure Description	SVR rate was the percentage of participants treated with at least one dose of study medication (PEG2a, Ribavirin, or Boceprevir/Placebo) who had achieved SVR. SVR was defined as undetectable Hepatitis C Virus-Ribonucleic Acid (HCV RNA).
Time Frame	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 Population: all randomized participants who received at least one dose of study medication (PEG2a, Ribavirin, or Boceprevir/Placebo). Follow-up (FU) Week (W) 12 value was Last Observation Carried Forward (LOCF), if last SVR value at or after FU W24 was not available.

Reporting Groups

	Description
PEG2a/Ribavirin	Peginterferon alfa-2a (PEG2a) (180 µg/week subcutaneously [SC]) plus ribavirin (1000 to 1200 mg/day orally [PO]) for 4 weeks followed by placebo (800 mg three times a day [TID] PO, using placebo matching SCH 503034 200-mg capsules) + PEG2a 180 µg/week SC plus ribavirin 1000 to 1200 mg/day PO divided twice daily (BID) for 48 weeks with 24 weeks post-treatment follow-up.
Boceprevir/PEG2a/Ribavirin	PEG2a (180 µg/week SC) plus ribavirin (1000 to 1200 mg/day PO) for 4 weeks followed by boceprevir (800 mg TID PO, using SCH 503034 200-mg capsules) + PEG2a 180 µg/week SC plus ribavirin 1000 to 1200 mg/day PO divided BID for 48 weeks with 24 weeks post-treatment follow-up.

Measured Values

	PEG2a/Ribavirin	Boceprevir/PEG2a/Ribavirin
Number of Participants Analyzed [units: participants]	67	134
Sustained Virologic Response (SVR) Rate in Full Analysis Set (FAS) Population. [units: Percentage of Participants]	20.9	64.2

No statistical analysis provided for Sustained Virologic Response (SVR) Rate in Full Analysis Set (FAS) Population.

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

Measure Type	Secondary
Measure Title	SVR Rate in the Modified Intent-to-Treat (mITT) Population
Measure Description	SVR rate was the percentage of participants treated with at least one dose of study medication (Boceprevir/PEG2a/Ribavirin or PEG2a/Ribavirin). Participants who discontinued study drugs during the 4-week PEG2a/Ribavirin lead-in period were not included in the mITT population.
Time Frame	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 Population: all randomized participants who received at least one dose of study medication (Boceprevir/PEG2a/Ribavirin or PEG2a/Ribavirin). Participants who discontinued study drugs during the 4-week PEG2a/Ribavirin lead-in period were not included. FU W12 value was LOCF, if last SVR value at or after FU W24 was not available.

Reporting Groups

	Description
PEG2a/Ribavirin	Peginterferon alfa-2a (PEG2a) (180 µg/week subcutaneously [SC]) plus ribavirin (1000 to 1200 mg/day orally [PO]) for 4 weeks followed by placebo (800 mg three times a day [TID] PO, using placebo matching SCH 503034 200-mg capsules) + PEG2a 180 µg/week SC plus ribavirin 1000 to 1200 mg/day PO divided twice daily (BID) for 48 weeks with 24 weeks post-treatment follow-up.
Boceprevir/PEG2a/Ribavirin	PEG2a (180 µg/week SC) plus ribavirin (1000 to 1200 mg/day PO) for 4 weeks followed by boceprevir (800 mg TID PO, using SCH 503034 200-mg capsules) + PEG2a 180 µg/week SC plus ribavirin 1000 to 1200 mg/day PO divided BID for 48 weeks with 24 weeks post-treatment follow-up.

Measured Values

	PEG2a/Ribavirin	**Boceprevir/PEG2a/Ribavirin**
Number of Participants Analyzed [units: participants]	**67**	**130**
SVR Rate in the Modified Intent-to-Treat (mITT) Population [units: Percentage of Participants]	**20.9**	**66.2**

No statistical analysis provided for SVR Rate in the Modified Intent-to-Treat (mITT) Population

3. Secondary: Percentage of Participants With Early Virologic Response (EVR) Who Achieved SVR [Time Frame: Day 1 to Treatment Week 12]

Measure Type	Secondary
Measure Title	Percentage of Participants With Early Virologic Response (EVR) Who Achieved SVR
Measure Description	EVR was defined as the time to the first undectectable HCV-RNA result at Treatment Week (TW) 2, 4, 8, or 12. Participants with a detectable, but not quantifiable HCV-RNA result at TW 12 may have undergone retesting. Participants with a detectable result on retesting were to be discontinued per the 12-week futility rule. Participants with an undetectable result on retesting were allowed to continue on treatment, and the detectable but not quantifiable result

	was to be considered a false positive.
Time Frame	Day 1 to Treatment Week 12
Safety Issue	No

Population Description

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

Reporting Groups

	Description
PEG2a/Ribavirin	Peginterferon alfa-2a (PEG2a) (180 µg/week subcutaneously [SC]) plus ribavirin (1000 to 1200 mg/day orally [PO]) for 4 weeks followed by placebo (800 mg three times a day [TID] PO, using placebo matching SCH 503034 200-mg capsules) + PEG2a 180 µg/week SC plus ribavirin 1000 to 1200 mg/day PO divided twice daily (BID) for 48 weeks with 24 weeks post-treatment follow-up.
Boceprevir/PEG2a/Ribavirin	PEG2a (180 µg/week SC) plus ribavirin (1000 to 1200 mg/day PO) for 4 weeks followed by boceprevir (800 mg TID PO, using SCH 503034 200-mg capsules) + PEG2a 180 µg/week SC plus ribavirin 1000 to 1200 mg/day PO divided BID for 48 weeks with 24 weeks post-treatment follow-up.

Measured Values

	PEG2a/Ribavirin	**Boceprevir/PEG2a/Ribavirin**
Number of Participants Analyzed [units: participants]	**67**	**134**
Percentage of Participants With Early Virologic Response (EVR) Who Achieved SVR [units: Percentage of Participants]		
<=TW 4 (PEG2a N = 2, Boceprevir N = 3)	**50.0**	**100.0**
>TW 4 to TW 8 (PEG2a N = 7, Boceprevir N = 76)	**42.9**	**82.9**
>TW 8 to TW 12 (PEG2a N = 9, Boceprevir N = 22)	**88.9**	**68.2**

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

4. Secondary: Number of Participants With Undetectable HCV-RNA at Follow-up Week 12 [Time Frame: Follow-up Week 12]

Measure Type	Secondary
Measure Title	Number of Participants With Undetectable HCV-RNA at Follow-up Week 12
Measure Description	No text entered.
Time Frame	Follow-up Week 12
Safety Issue	No

Population Description

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

Reporting Groups

	Description
PEG2a/Ribavirin	Peginterferon alfa-2a (PEG2a) (180 µg/week subcutaneously [SC]) plus ribavirin (1000 to 1200 mg/day orally [PO]) for 4 weeks followed by placebo (800 mg three times a day [TID] PO, using placebo matching SCH 503034 200-mg capsules) + PEG2a 180 µg/week SC plus ribavirin 1000 to 1200 mg/day PO divided twice daily (BID) for 48 weeks with 24 weeks post-treatment follow-up.
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Measured Values

	PEG2a/Ribavirin	Boceprevir/PEG2a/Ribavirin
Number of Participants Analyzed [units: participants]	**67**	**134**
Number of Participants With Undetectable HCV-RNA at Follow-up Week 12 [units: Participants]	**12**	**87**

No statistical analysis provided for Number of Participants With Undetectable HCV-RNA at Follow-up Week 12

5. Secondary: Mean Log Change From Baseline to TW 4 in Viral Load by Visit [Time Frame: From Baseline to TW 4]

Measure Type	Secondary
Measure Title	Mean Log Change From Baseline to TW 4 in Viral Load by Visit
Measure Description	HCV-RNA levels were quantified using the Roche Cobas Taqman 1.0 assay; lower limit of detection of 15 international units [IU]/mL. Changes in HCV-RNA IU/ml were expressed on a log10 scale.
Time Frame	From Baseline to TW 4
Safety Issue	No

Population Description

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

Reporting Groups

	Description
PEG2a/Ribavirin	Peginterferon alfa-2a (PEG2a) (180 µg/week subcutaneously [SC]) plus ribavirin (1000 to 1200 mg/day orally [PO]) for 4 weeks followed by placebo (800 mg three times a day [TID] PO, using placebo matching SCH 503034 200-mg capsules) + PEG2a 180 µg/week SC plus ribavirin 1000 to 1200 mg/day PO divided twice daily (BID) for 48 weeks with 24 weeks post-treatment follow-up.
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Measured Values

	PEG2a/Ribavirin	Boceprevir/PEG2a/Ribavirin
Number of Participants Analyzed [units: participants]	67	134
Mean Log Change From Baseline to TW 4 in Viral Load by Visit [units: log10 (IU/mL)] Mean (Standard Deviation)	-2.44 (1.32)	-2.33 (1.34)

No statistical analysis provided for Mean Log Change From Baseline to TW 4 in Viral Load by Visit

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
PEG2a/Ribavirin	Peginterferon alfa-2a (PEG2a) (180 µg/week subcutaneously [SC]) plus ribavirin (1000 to 1200 mg/day orally [PO]) for 4 weeks followed by placebo (800 mg three times a day [TID] PO, using placebo matching SCH 503034 200-mg capsules) + PEG2a 180 µg/week SC plus ribavirin 1000 to 1200 mg/day PO divided twice daily (BID) for 48 weeks with 24 weeks post-treatment follow-up.
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Serious Adverse Events

	PEG2a/Ribavirin	Boceprevir/PEG2a/Ribavirin
Total, serious adverse events		
# participants affected / at risk	**7/67 (10.45%)**	**18/134 (13.43%)**
Blood and lymphatic system disorders		
NEUTROPENIA † 1		
# participants affected / at risk	**0/67 (0.00%)**	**2/134 (1.49%)**
# events	**0**	**3**
THROMBOCYTOPENIA † 1		
# participants affected / at risk	**0/67 (0.00%)**	**1/134 (0.75%)**
# events	**0**	**1**
Cardiac disorders		
CARDIAC FAILURE † 1		
# participants affected / at risk	**0/67 (0.00%)**	**1/134 (0.75%)**
# events	**0**	**1**

CORONARY ARTERY DISEASE † 1		
# participants affected / at risk	**0/67 (0.00%)**	**1/134 (0.75%)**
# events	**0**	**1**
Gastrointestinal disorders		
DIARRHOEA † 1		
# participants affected / at risk	**0/67 (0.00%)**	**1/134 (0.75%)**
# events	**0**	**1**
UPPER GASTROINTESTINAL HAEMORRHAGE † 1		
# participants affected / at risk	**0/67 (0.00%)**	**1/134 (0.75%)**
# events	**0**	**1**
General disorders		
ASTHENIA † 1		
# participants affected / at risk	**0/67 (0.00%)**	**1/134 (0.75%)**
# events	**0**	**1**
CHEST PAIN † 1		
# participants affected / at risk	**1/67 (1.49%)**	**0/134 (0.00%)**
# events	**1**	**0**
IRRITABILITY † 1		
# participants affected / at risk	**1/67 (1.49%)**	**0/134 (0.00%)**
# events	**1**	**0**
MULTI-ORGAN FAILURE † 1		
# participants affected / at risk	**0/67 (0.00%)**	**1/134 (0.75%)**
# events	**0**	**1**
PYREXIA † 1		
# participants affected / at risk	**0/67 (0.00%)**	**1/134 (0.75%)**
# events	**0**	**2**
Infections and infestations		
BRONCHITIS † 1		
# participants affected / at risk	**0/67 (0.00%)**	**1/134 (0.75%)**
# events	**0**	**1**
CELLULITIS † 1		
# participants affected / at risk	**0/67 (0.00%)**	**1/134 (0.75%)**
# events	**0**	**1**
CHLAMYDIAL INFECTION † 1		
# participants affected / at risk	**0/67 (0.00%)**	**1/134 (0.75%)**
# events	**0**	**1**
INFLUENZA † 1		
# participants affected / at risk	**0/67 (0.00%)**	**1/134 (0.75%)**
# events	**0**	**1**
PNEUMONIA † 1		
# participants affected / at risk	**0/67 (0.00%)**	**2/134 (1.49%)**
# events	**0**	**2**
PNEUMONIA STAPHYLOCOCCAL † 1		
# participants affected / at risk	**0/67 (0.00%)**	**1/134 (0.75%)**

# events	0	1
STAPHYLOCOCCAL BACTERAEMIA † 1		
# participants affected / at risk	0/67 (0.00%)	1/134 (0.75%)
# events	0	1
STAPHYLOCOCCAL INFECTION † 1		
# participants affected / at risk	0/67 (0.00%)	1/134 (0.75%)
# events	0	1
UROSEPSIS † 1		
# participants affected / at risk	0/67 (0.00%)	1/134 (0.75%)
# events	0	1
Injury, poisoning and procedural complications		
FOREIGN BODY † 1		
# participants affected / at risk	1/67 (1.49%)	0/134 (0.00%)
# events	1	0
GUN SHOT WOUND † 1		
# participants affected / at risk	0/67 (0.00%)	1/134 (0.75%)
# events	0	1
Metabolism and nutrition disorders		
HYPONATRAEMIA † 1		
# participants affected / at risk	0/67 (0.00%)	2/134 (1.49%)
# events	0	2
Musculoskeletal and connective tissue disorders		
INTERVERTEBRAL DISC PROTRUSION † 1		
# participants affected / at risk	1/67 (1.49%)	0/134 (0.00%)
# events	1	0
Nervous system disorders		
LETHARGY † 1		
# participants affected / at risk	0/67 (0.00%)	1/134 (0.75%)
# events	0	1
NEURALGIA † 1		
# participants affected / at risk	1/67 (1.49%)	0/134 (0.00%)
# events	1	0
SUBARACHNOID HAEMORRHAGE † 1		
# participants affected / at risk	0/67 (0.00%)	1/134 (0.75%)
# events	0	1
SYNCOPE † 1		
# participants affected / at risk	0/67 (0.00%)	2/134 (1.49%)
# events	0	2
Psychiatric disorders		
ABNORMAL BEHAVIOUR † 1		
# participants affected / at risk	1/67 (1.49%)	0/134 (0.00%)
# events	1	0
ANXIETY † 1		
# participants affected / at risk	1/67 (1.49%)	0/134 (0.00%)

# events	1	0
MENTAL STATUS CHANGES † 1		
# participants affected / at risk	0/67 (0.00%)	1/134 (0.75%)
# events	0	1
SUICIDAL IDEATION † 1		
# participants affected / at risk	0/67 (0.00%)	1/134 (0.75%)
# events	0	1
Renal and urinary disorders		
RENAL COLIC † 1		
# participants affected / at risk	1/67 (1.49%)	0/134 (0.00%)
# events	1	0
Surgical and medical procedures		
OSTEOTOMY † 1		
# participants affected / at risk	1/67 (1.49%)	0/134 (0.00%)
# events	1	0
Vascular disorders		
DEEP VEIN THROMBOSIS † 1		
# participants affected / at risk	0/67 (0.00%)	1/134 (0.75%)
# events	0	1

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.1

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
PEG2a/Ribavirin	Peginterferon alfa-2a (PEG2a) (180 µg/week subcutaneously [SC]) plus ribavirin (1000 to 1200 mg/day orally [PO]) for 4 weeks followed by placebo (800 mg three times a day [TID] PO, using placebo matching SCH 503034 200-mg capsules) + PEG2a 180 µg/week SC plus ribavirin 1000 to 1200 mg/day PO divided twice daily (BID) for 48 weeks with 24 weeks post-treatment follow-up.
Boceprevir/PEG2a/Ribavirin	PEG2a (180 µg/week SC) plus ribavirin (1000 to 1200 mg/day PO) for 4 weeks followed by boceprevir (800 mg TID PO, using SCH 503034 200-mg capsules) + PEG2a 180 µg/week SC plus ribavirin 1000 to 1200 mg/day PO divided BID for 48 weeks with 24 weeks post-treatment follow-up.

Other Adverse Events

	PEG2a/Ribavirin	Boceprevir/PEG2a/Ribavirin

Total, other (not including serious) adverse events		
# participants affected / at risk	**67/67 (100.00%)**	**133/134 (99.25%)**
Blood and lymphatic system disorders		
ANAEMIA † 1		
# participants affected / at risk	**22/67 (32.84%)**	**67/134 (50.00%)**
# events	**32**	**119**
LEUKOPENIA † 1		
# participants affected / at risk	**2/67 (2.99%)**	**20/134 (14.93%)**
# events	**3**	**43**
NEUTROPENIA † 1		
# participants affected / at risk	**12/67 (17.91%)**	**41/134 (30.60%)**
# events	**17**	**89**
THROMBOCYTOPENIA † 1		
# participants affected / at risk	**4/67 (5.97%)**	**9/134 (6.72%)**
# events	**6**	**12**
Eye disorders		
DRY EYE † 1		
# participants affected / at risk	**1/67 (1.49%)**	**9/134 (6.72%)**
# events	**1**	**9**
Gastrointestinal disorders		
ABDOMINAL PAIN † 1		
# participants affected / at risk	**0/67 (0.00%)**	**7/134 (5.22%)**
# events	**0**	**8**
ABDOMINAL PAIN UPPER † 1		
# participants affected / at risk	**4/67 (5.97%)**	**11/134 (8.21%)**
# events	**5**	**12**
CONSTIPATION † 1		
# participants affected / at risk	**5/67 (7.46%)**	**5/134 (3.73%)**
# events	**5**	**5**
DIARRHOEA † 1		
# participants affected / at risk	**5/67 (7.46%)**	**33/134 (24.63%)**
# events	**5**	**38**
DRY MOUTH † 1		
# participants affected / at risk	**2/67 (2.99%)**	**7/134 (5.22%)**
# events	**2**	**7**
DYSPEPSIA † 1		
# participants affected / at risk	**3/67 (4.48%)**	**10/134 (7.46%)**
# events	**3**	**11**
NAUSEA † 1		
# participants affected / at risk	**18/67 (26.87%)**	**52/134 (38.81%)**
# events	**19**	**60**
VOMITING † 1		

# participants affected / at risk	0/67 (0.00%)	16/134 (11.94%)
# events	0	21
General disorders		
ASTHENIA † 1		
# participants affected / at risk	12/67 (17.91%)	29/134 (21.64%)
# events	15	47
CHILLS † 1		
# participants affected / at risk	8/67 (11.94%)	14/134 (10.45%)
# events	8	24
FATIGUE † 1		
# participants affected / at risk	36/67 (53.73%)	67/134 (50.00%)
# events	43	80
INFLUENZA LIKE ILLNESS † 1		
# participants affected / at risk	18/67 (26.87%)	35/134 (26.12%)
# events	18	37
INJECTION SITE ERYTHEMA † 1		
# participants affected / at risk	4/67 (5.97%)	9/134 (6.72%)
# events	4	9
IRRITABILITY † 1		
# participants affected / at risk	16/67 (23.88%)	29/134 (21.64%)
# events	17	34
OEDEMA PERIPHERAL † 1		
# participants affected / at risk	3/67 (4.48%)	7/134 (5.22%)
# events	3	8
PAIN † 1		
# participants affected / at risk	2/67 (2.99%)	9/134 (6.72%)
# events	2	10
PYREXIA † 1		
# participants affected / at risk	8/67 (11.94%)	18/134 (13.43%)
# events	8	39
Infections and infestations		
INFLUENZA † 1		
# participants affected / at risk	0/67 (0.00%)	8/134 (5.97%)
# events	0	8
Investigations		
WEIGHT DECREASED † 1		
# participants affected / at risk	4/67 (5.97%)	11/134 (8.21%)
# events	4	12
Metabolism and nutrition disorders		
DECREASED APPETITE † 1		
# participants affected / at risk	12/67 (17.91%)	27/134 (20.15%)
# events	12	28
Musculoskeletal and connective tissue disorders		
ARTHRALGIA † 1		

# participants affected / at risk	12/67 (17.91%)	16/134 (11.94%)
# events	15	22
BACK PAIN † 1		
# participants affected / at risk	5/67 (7.46%)	10/134 (7.46%)
# events	6	12
MUSCLE SPASMS † 1		
# participants affected / at risk	5/67 (7.46%)	14/134 (10.45%)
# events	7	16
MYALGIA † 1		
# participants affected / at risk	5/67 (7.46%)	25/134 (18.66%)
# events	5	32
PAIN IN EXTREMITY † 1		
# participants affected / at risk	1/67 (1.49%)	7/134 (5.22%)
# events	1	8
Nervous system disorders		
DISTURBANCE IN ATTENTION † 1		
# participants affected / at risk	4/67 (5.97%)	8/134 (5.97%)
# events	4	9
DIZZINESS † 1		
# participants affected / at risk	10/67 (14.93%)	17/134 (12.69%)
# events	10	19
DYSGEUSIA † 1		
# participants affected / at risk	10/67 (14.93%)	52/134 (38.81%)
# events	10	53
HEADACHE † 1		
# participants affected / at risk	21/67 (31.34%)	37/134 (27.61%)
# events	25	46
Psychiatric disorders		
ANXIETY † 1		
# participants affected / at risk	9/67 (13.43%)	16/134 (11.94%)
# events	9	18
DEPRESSION † 1		
# participants affected / at risk	6/67 (8.96%)	22/134 (16.42%)
# events	7	28
INSOMNIA † 1		
# participants affected / at risk	20/67 (29.85%)	32/134 (23.88%)
# events	21	36
SLEEP DISORDER † 1		
# participants affected / at risk	3/67 (4.48%)	15/134 (11.19%)
# events	4	16
Respiratory, thoracic and mediastinal disorders		
COUGH † 1		
# participants affected / at risk	14/67 (20.90%)	26/134 (19.40%)
# events	16	32
DYSPNOEA † 1		

# participants affected / at risk	17/67 (25.37%)	26/134 (19.40%)
# events	17	28
DYSPNOEA EXERTIONAL † 1		
# participants affected / at risk	5/67 (7.46%)	13/134 (9.70%)
# events	5	16
OROPHARYNGEAL PAIN † 1		
# participants affected / at risk	1/67 (1.49%)	13/134 (9.70%)
# events	1	15
Skin and subcutaneous tissue disorders		
ALOPECIA † 1		
# participants affected / at risk	5/67 (7.46%)	22/134 (16.42%)
# events	5	24
DRY SKIN † 1		
# participants affected / at risk	11/67 (16.42%)	20/134 (14.93%)
# events	13	22
PRURITUS † 1		
# participants affected / at risk	8/67 (11.94%)	18/134 (13.43%)
# events	9	23
RASH † 1		
# participants affected / at risk	5/67 (7.46%)	31/134 (23.13%)
# events	5	37

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.1

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 present any interim results of study without prior written consent of sponsor. Investigator agrees to provide sponsor 45 days prior to submission publication, review copies of abstracts/manuscripts that report any results of the study. Sponsor shall have the right to review/comment on data analysis. If parties disagree investigator agrees to meet with sponsor's representatives at clinical study site for purpose of making good faith efforts to resolve any such issues.

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):

Flamm SL, Lawitz E, Jacobson I, Bourlière M, Hezode C, Vierling JM, Bacon BR, Niederau C, Sherman M, Goteti V, Sings HL, Barnard RO, Howe JA, Pedicone LD, Burroughs MH, Brass CA, Albrecht JK, Poordad F. Boceprevir with peginterferon alfa-2a-ribavirin is effective for previously treated chronic hepatitis C genotype 1 infection. Clin Gastroenterol Hepatol. 2013 Jan;11(1):81-87.e4; quiz e5. doi: 10.1016/j.cgh.2012.10.006. Epub 2012 Oct 10.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00845065 History of Changes
Other Study ID Numbers:	P05685
Study First Received:	February 13, 2009
Results First Received:	October 10, 2011
Last Updated:	September 24, 2015
Health Authority:	United States: Food and Drug Administration

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