Boceprevir plus peginterferon/ribavirin for treatment of chronic hepatitis C in Russia

Vasily Isakov, Igor Nikitin, Vladimir Chulanov, Pavel Ogurtsov, Ekaterina Lukyanova, Jianmin Long, Janice Wahl, Frans A. Helmond, for the P08160 Trial Investigators

This study is registered at

https://clinicaltrials.gov/ct2/show/NCT01425203

The registration identification number is NCT01425203

The Effect of Boceprevir in Russian Participants Diagnosed With Chronic Hepatitis C Genotype 1 (P08160)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT01425203

First received: August 26, 2011
Last updated: September 3, 2014
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History of Changes

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Purpose

The purpose of this study is to determine whether Boceprevir (BOC, SCH 503034, MK-3034) in combination with Peginterferon Alfa 2-b (PEG) plus Ribavirin (RBV) [PEG+RBV=PR] is effective in the treatment of chronic hepatitis C (CHC) genotype 1 among the Russian population. The primary hypothesis is that the percentage of participants achieving sustained virologic response in the BOC + PR group is superior to that in the Placebo (PBO) + PR group.

Condition	Intervention	Phase
Chronic Hepatitis C Genotype 1	Drug: Boceprevir Drug: Placebo Biological: peginterferon alfa-2b Drug: Ribavirin	Phase 3

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

Official Title: Safety and Efficacy of Boceprevir in Combination With Peginterferon Alfa-2b Plus Ribavirin for Treatment of Chronic Hepatitis C Genotype 1 in Russia: Previously Untreated Patients and Patients Who Failed Prior Treatment With Pegylated-Interferon Plus Ribavirin

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 Achieving Sustained Virologic Response At Follow-up Week 24 (SVR24) Among Participants Who Received At Least One Dose of Any Trial Medication (Full Analysis Set Population) [Time Frame: Follow-up Week 24 (up to 72 weeks)] [Designated as safety issue: No]

  SVR24 was defined as an undetectable plasma Hepatitis C Virus-ribonucleic acid (HCV-RNA) level at Follow-up Week 24 (FW24). If a participant was missing FW24 data and had undetectable HCV-RNA at FW12, the participant was considered a sustained virologic responder.

Secondary Outcome Measures:

- Percentage of Participants Achieving SVR24 Among Participants Who Received At Least One Dose of Experimental Trial Drug (Modified Intent-To-Treat [mITT] Population) [Time Frame: Follow-up Week 24 (up to 72 weeks)] [Designated as safety issue: No]

  SVR24 was defined as an undetectable plasma HCV-RNA level at FW24. If a participant was missing FW24 data and had undetectable HCV-RNA at FW12, the participant was considered a sustained virologic responder.

- Percentage of Participants Achieving Early Virologic Response (EVR) At Treatment Week (TW) 8 [Time Frame: Treatment Week 8] [Designated as safety issue: No]

  EVR was defined as an undetectable HCV-RNA level at TW 8. This analysis was conducted when all participants had completed 8 weeks of the study or had discontinued prior to TW 8.

Enrollment:	238
Study Start Date:	November 2011
Study Completion Date:	October 2013
Primary Completion Date:	October 2013 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: RGT BOC + PR Participants received PR for 4 weeks before addition of BOC. Participants then received response guided therapy (RGT) with BOC + PR for up to 32 weeks followed by PBO + PR for up to 20 weeks.	Drug: Boceprevir boceprevir 200-mg capsules, 800 mg 3 times a day (TID), orally (PO) Other Name: SCH 503034 Biological: peginterferon alfa-2b peginterferon alfa-2b 1.5 µg/kg/wk subcutaneously (SC) Other Name: PegIntron Drug: Ribavirin ribavirin (weight-based dosing) 800 to 1400 mg/day PO divided twice daily dose (BID).
Placebo Comparator: PBO + PR (Control) Participants received PR for 4 weeks before addition of BOC-matched PBO. Participants then received BOC + PR for up to 44 weeks.	Drug: Placebo boceprevir-matched placebo four 200-mg capsules PO TID. Biological: peginterferon alfa-2b peginterferon alfa-2b 1.5 µg/kg/wk subcutaneously (SC) Other Name: PegIntron Drug: Ribavirin ribavirin (weight-based dosing) 800 to 1400 mg/day PO divided twice daily dose (BID).
Experimental: Crossover Arm Participants randomized to the PBO + PR Control arm who failed the futility rule at treatment week (TW) 12 or 24 were rolled over to the Crossover arm and received BOC + PR.	Drug: Boceprevir boceprevir 200-mg capsules, 800 mg 3 times a day (TID), orally (PO)

	Other Name: SCH 503034 Biological: peginterferon alfa-2b peginterferon alfa-2b 1.5 µg/kg/wk subcutaneously (SC) Other Name: PegIntron Drug: Ribavirin ribavirin (weight-based dosing) 800 to 1400 mg/day PO divided twice daily dose (BID).

Eligibility

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

Criteria

Inclusion criteria:

- body weight ≥40 kg and ≤125 kg
- previously documented CHC genotype 1 infection;
- must have a liver biopsy with histology consistent with CHC and no other etiology
- if cirrhosis present, 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)
- agree to use acceptable methods of contraception with partner
- previously untreated with pegylated-interferon (either alfa-2a or alfa-2b) plus RBV or failing prior treatment with pegylated-interferon (either alfa-2a or alfa-2b) plus RBV

Exclusion criteria:

- co-infected with the human immunodeficiency virus (HIV) or hepatitis B virus (Hepatitis B surface antigen [HBsAg] positive).
- required discontinuation of previous interferon or ribavirin regimen for an adverse event (possibly or probably related)
- treatment with ribavirin within 90 days and any interferon-alpha, based on the amendment, should be within 1 month prior to screening
- treatment with any investigational drug within 30 days of the screening visit in this 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 with clinically significant ocular examination findings
- clinical diagnosis of substance abuse of specified drugs within specified timeframes
- any known pre-existing medical condition that could interfere with the participant's participation in and completion of the trial

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.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01425203

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Director Merck Sharp & Dohme Corp.

More Information

No publications provided

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT01425203 History of Changes
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Results First Received:	July 29, 2014
Last Updated:	September 3, 2014
Health Authority:	Russia: Ministry of Health of the Russian Federation

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

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