A Phase 3 Evaluation of Daclatasvir and Asunaprevir in Treatment-naive Subjects With Chronic Hepatitis C Genotype 1b Infection

ClinicalTrials.gov Identifier: NCT02496078

Recruitment Status : Completed
First Posted : July 14, 2015
Last Update Posted : April 19, 2017

Sponsor:
Bristol-Myers Squibb

Information provided by (Responsible Party):
Bristol-Myers Squibb

Study Description

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Brief Summary:
The purpose of this study is to determine whether a regimen consisting of daclatasvir and asunaprevir is effective in treatment-naive patients with chronic hepatitis genotype 1b infection.

Condition or disease	Intervention/treatment	Phase
Hepatitis C	Drug: Daclatasvir Drug: Asunaprevir	Phase 3

Study Design

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Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	207 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Primary Purpose:	Treatment
Official Title:	A Phase 3 Evaluation of Daclatasvir and Asunaprevir in Treatment-naive Subjects With Chronic Hepatitis C Genotype 1b Infection
Study Start Date :	August 2015
Primary Completion Date :	August 2016
Study Completion Date :	February 2017

Resource links provided by the National Library of Medicine NIH NLM

MedlinePlus related topics: Hepatitis Hepatitis A Hepatitis C

Drug Information available for: Daclatasvir

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Active Comparator: Active dual arm Daclatasvir in tablet form at the dose of 60 mg QD and Asunaprevir in soft capsule form at the dose of 100 mg BID from day 1 to 12 week Daclatasvir in tablet form at the dose of 60 mg QD and Asunaprevir in soft capsule form at the dose of 100 mg BID from 12 to 24 week and follow up to week 48	Drug: Daclatasvir Daclatasvir tablet 60mg Drug: Asunaprevir Asunaprevir soft capsule 100 mg
Placebo Comparator: Placebo arm Daclatasvir placebo in tablet form QD and Asunaprevir placebo in soft capsule form BID from day 1 to 12 week	Drug: Daclatasvir Daclatasvir tablet 60mg Drug: Asunaprevir

Daclatasvir in tablet form at the dose of 60 mg QD and Asunaprevir in soft capsule form at the dose of 100 mg BID from 12 to 36 week and follow up to week 60	Asunaprevir soft capsule 100 mg

Outcome Measures

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Primary Outcome Measures :

1. Proportion of treated subjects randomized to Active Dual therapy with Sustained Virologic Response (SVR12) [Time Frame: Post-treatment Week 12]

   HCV RNA < Lower limit of quantitation (LLOQ) target detected (TD) or target not detected (TND) at follow-up Week 12

Secondary Outcome Measures :

1. Proportion of subjects with anemia on active Dual therapy [Time Frame: Post-treatment Week 12]
2. Proportion of subjects with neutropenia on active Dual therapy [Time Frame: Post-treatment Week 12]
3. Proportion of subjects with thrombocytopenia on active Dual therapy [Time Frame: Post-treatment Week 12]
4. On treatment safety, as measured by frequency of serious adverse events (SAEs) and discontinuations due to adverse events (AEs) [Time Frame: Post-treatment week 12]
5. Differences in rates of selected Grade 3-4 laboratory abnormalities for hematology between treatments (DCV + Asunaprevir (ASV) vs PBO) [Time Frame: first 12 weeks on treatment]
6. Differences in rates of selected Grade 3-4 laboratory abnormalities for liver function between treatments (DCV + Asunaprevir (ASV) vs PBO) [Time Frame: first 12 weeks on treatment]
7. Proportion of subjects with SVR12 by the rs12979860 single nucleotide polymorphism (SNP) in the interleukin (IL) -28B gene for each cohort [Time Frame: Post-treatment visit week 12]
8. Proportion of subjects with hepatitis C virus (HCV) RNA < LLOQ-TD/TND in each arm at various intervals after the initiation of active Dual therapy [Time Frame: post-treatment visit Week 24]
9. Proportion of subjects who achieve HCV RNA < LLOQ-TND at each arm at various intervals after the initiation of active Dual therapy [Time Frame: post-treatment visit Week 24]
10. Proportion of treated subjects with SVR12 for subjects randomized to placebo [Time Frame: Post-treatment visit week 12]

Eligibility Criteria

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Information from the National Library of Medicine NIH NLM

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, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

For more information regarding BMS clinical trial participation, please visit www.BMSStudyConnect.com

Inclusion Criteria:

- Patients chronically infected with HCV Genotype 1b
- No previous exposure to any interferon formulation, Ribavirin (RBV), and HCV direct acting antiviral agent
- HCV RNA viral load ≥ 10,000 IU/mL at screening
- Seronegative for HIV and HBsAg
- BMI of 18-35 kg/m2, inclusive
- Patients with compensated cirrhosis are permitted

Exclusion Criteria:

- Infection with HCV other than genotype (GT) -1b
- Evidence of decompensated liver disease including, but not limited to, a history or presence of ascites, bleeding varices, or hepatic encephalopathy
- Evidence of a medical condition contributing to chronic liver disease other than HCV
- Diagnosed or suspected hepatocellular carcinoma or other malignancies
- Uncontrolled diabetes or hypertension
- History of moderate to severe depression. Well-controlled mild depression is allowed
- Confirmed alanine aminotransferase (ALT) ≥ 5x Upper Limit of Normal (ULN)
- Confirmed platelet count < 50,000 cells/mm3

- Confirmed hemoglobin < 8.5 g/dL

Contacts and Locations

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Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02496078***

Show 29 Study Locations

Sponsors and Collaborators

Bristol-Myers Squibb

Investigators

Study Director: Bristol-Myers Squibb Bristol-Myers Squibb

More Information

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Additional Information:

BMS Clinical Trial Information EXIT

BMS clinical trial educational resource EXIT

Investigator Inquiry form EXIT

FDA Safety Alerts and Recalls EXIT

Responsible Party:	Bristol-Myers Squibb
ClinicalTrials.gov Identifier:	NCT02496078 History of Changes
Other Study ID Numbers:	AI447-114
First Posted:	July 14, 2015 Key Record Dates
Last Update Posted:	April 19, 2017
Last Verified:	September 2016

Additional relevant MeSH terms:

Hepatitis
Hepatitis A
Hepatitis C
Hepatitis, Chronic
Hepatitis C, Chronic
Liver Diseases
Digestive System Diseases
Hepatitis, Viral, Human
Virus Diseases
Enterovirus Infections
Picornaviridae Infections
RNA Virus Infections
Flaviviridae Infections