Seladelpar in Subjects With Primary Biliary Cholangitis (PBC) and Compensated Cirrhosis

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

Individuals must meet the following criteria to be eligible for study participation: 1. Must be at least 18 years old. 2. Must have a confirmed prior diagnosis of PBC 3. Evidence of cirrhosis 4. CP Score A or B 5. Females of reproductive potential must use at least 1 barrier contraceptive and a second effective birth control method during the study and for at least 90 days after the last dose. Male individuals who are sexually active with female partners of reproductive potential must use barrier contraception, and their female partners must use a second effective birth control method during the study and for at least 90 days after the last dose 6. Individuals must be able to comply with the instructions for study drug administration and be able to complete the study schedule of assessments (SOA)

Exclusion Criteria:

Individuals must not meet any of the following criteria to be eligible for study participation: 1. Prior exposure to seladelpar 2. A medical condition other than PBC that, in the Investigator's opinion, would preclude full participation in the study 3. History of liver transplantation or actively listed for cadaveric or planned living donor transplant. 4. Decompensated cirrhosis 5. Evidence of portal vein thrombosis based on imaging at time of Screening by Doppler ultrasound or prior evidence by CT or MRI 6. Hospitalization for liver-related complication within 12 weeks of Screening 7. Laboratory parameters at Screening: 1. Alkaline phosphatase (ALP) \< 1.5× Upper limit of normal (ULN) or ≥ 10×ULN 2. Alanine aminotransferase (ALT) or Aspartate aminotransferase (AST) ≥5×ULN 3. Total bilirubin (TB) ≥5×ULN 4. Platelet count ≤50×10\^3/µL 5. Albumin ≤2.8 g/dL 6. Estimated glomerular filtration rate (eGFR) \<45 mL/min/1.73 m\^2 7. MELD score \>12. For individuals on anticoagulation medication, baseline International normalized ratio (INR) determination for MELD score calculation should take anticoagulant use into account, in consultation with the Medical Monitor. 8. Serum alpha-fetoprotein (AFP) \>20 ng/mL 9. INR \>1.7 8. CP-C cirrhosis 9. History or presence of other concomitant liver diseases

Conditions & Interventions

Interventions:
DRUG: Seladelpar, DRUG: Placebo
Conditions:
Primary Biliary Cholangitis
Keywords:
Primary Biliary Cholangitis (PBC), PBC

More Information

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IRB
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