A Long-Term Study of Elafibranor in Adult Participants With Primary Biliary Cholangitis

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria : * Male or female participants must be ≥18 years of age at the time of signing the informed consent. * Participants with a definite or probable diagnosis of primary biliary cholangitis (PBC) * Participants with cirrhosis at SV1. • Participants must be Child Pugh A or Child Pugh B. * Contraceptive use by men or women should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies. * Capable of giving signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol. Exclusion Criteria : * History or presence of other concomitant liver disease including but not limited to: * i) Primary sclerosing cholangitis (PSC). * ii) Autoimmune hepatitis (AIH) by simplified Diagnostic Criteria of the International Autoimmune Hepatitis Group (IAIHG) ≥6, or if treated for an overlap of PBC with AIH, or if there is clinical suspicion and evidence of overlap AIH features, that cannot be explained alone by insufficient response to UDCA. * iii) Positive hepatitis B surface antigen (HBsAg). Participants with negative HBsAg and positive hepatitis B core antibody (HBcAb) may be eligible if hepatitis B virus deoxyribonucleic acid (HBV DNA) is negative. * iv) Hepatitis C virus (HCV) infection defined by positive anti-HCV antibody and positive HCV ribonucleic acid (RNA) (Note: Participants with positive anti-HCV antibody due to previously treated HCV infection, may be enrolled if a confirmatory HCV RNA is undetectable and sustained viral response has been documented). * v) Alcohol-associated liver disease (ALD). * vi) Nonalcoholic steatohepatitis (NASH). * vii) Other chronic liver diseases, such as alpha-1 antitrypsin deficiency. * History or presence of clinically significant hepatic decompensation, including: * i) History of liver transplantation, current placement on a liver transplant list, current model for end-stage liver disease including (MELD) 3.0 score \>12 due to hepatic impairment. * ii) Evidence of complications of cirrhosis, including hepatic decompensation or evidence of significant portal hypertension complications including presence of uncontrolled ascites; history of variceal bleeding or related interventions (e.g. variceal banding, or transjugular intrahepatic portosystemic shunt placement); presence of hepatic encephalopathy Grade 2 or higher per West-Haven criteria; history or presence of spontaneous bacterial peritonitis. Note: participants with low-risk varices (Grade I) without history of bleeding or other treatment may be eligible to enrol. * iii) Hepatorenal syndrome (HRS) (type I or II). • vi) Hospitalisation for liver-related complication within 12 weeks prior to SV1. * Known history of human immunodeficiency virus (HIV) infection or having a positive confirmatory test for HIV type 1 or 2. * Medical conditions that may cause non-hepatic increases in ALP (e.g. Paget's disease). * Evidence of any other unstable or untreated clinically significant immunological, endocrine, hematologic, gastrointestinal, neurological, or psychiatric disease as evaluated by the investigator; other clinically significant conditions that are not well controlled. * Non-hepatic medical conditions that may diminish life expectancy to \<2 years, including known cancers. * History of hepatocellular carcinoma. * Alpha-fetoprotein (AFP) \>20 ng/mL with 4-phase liver computerised tomography (CT) or magnetic resonance imaging (MRI) imaging suggesting presence of hepatocellular carcinoma. * Known malignancy or history of malignancy within the last 5 years, with the exception of local, successfully treated basal cell carcinoma or in-situ carcinoma of the uterine cervix. * Administration of the following medications is prohibited during the study, and prior to the study as per the timelines specified below: • i) 3 months prior to screening period: fibrates, seladelpar, glitazones, obeticholic acid, azathioprine, cyclosporine, methotrexate, mycophenolate, pentoxifylline, budesonide and other systemic corticosteroids (parenteral and oral chronic administration only); potentially hepatotoxic drugs (including α-methyl-dopa, sodium valproic acid, isoniazid or nitrofurantoin). * Participants who are currently participating in, plan to participate in, or have participated in an investigational drug study or medical device study containing active substance within 30 days or 5 half-lives, whichever is longer, prior to the screening period. i) If the previous study was for an experimental therapy being studied for potential benefit in PBC, and the potential therapeutic agent was proven to have no beneficial effect in PBC and there are no safety concerns, the participant may enrol after 30 days or 5 half-lives from the last dose of the therapeutic agent, whichever is longer.ii) For therapeutic agents being studied for potential benefit in PBC for which it is still unclear if there may be a potential benefit, participants may enrol after 6 months from the last dose of the therapeutic agent. * Electrocardiogram (ECG) with QT interval corrected by Fridericia's formula (QTcF) \>450 msec in males or QTcF \>470 msec in females for participants without bundle branch block. For participants with bundle branch block or other intraventricular conduction delay, a longer QTcF \>480 msec would be exclusionary. * Total bilirubin (TB) \>5x ULN * Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) \>5x ULN at SV1 * Creatinine phosphokinase (CPK) \>2x ULN. * Platelet count \<50,000/µL * International normalised ratio (INR) \>1.8 in the absence of anticoagulant therapy. * Estimated glomerular filtration rate (eGFR) \<45 mL/min/1.73m2 per the Modification of Diet in Renal Disease (MDRD)-6 Study formula at SV1. * Significant renal disease, including nephritic syndrome, chronic kidney disease (CKD) (defined as participants with evidence of significantly impaired kidney function or underlying kidney injury). * For female participants: known current pregnancy, or has a positive serum pregnancy test, or is breastfeeding. * Participants unwilling or unable to be abstinent from alcohol during the study. * History of alcohol abuse, or other substance abuse within 1 year prior to SV1. * Known hypersensitivity to elafibranor or to any of the excipients of the investigational product(s). * Mental instability or incompetence, such that the validity of informed consent or ability to be compliant with the study is uncertain. * Any other condition that, in the opinion of the investigator, would interfere with study participation or completion, or would put the participant at risk, including a potential participant assessed as being at high risk of noncompliance with the study. * Alkaline phosphatase (ALP) ≥10x ULN. * Albumin \<2.8 g/dL due to impaired hepatic function.

Conditions & Interventions

Interventions:

DRUG: Elafibranor, OTHER: Matched 80 mg placebo

Conditions:

Primary Biliary Cholangitis (PBC)

More Information

Contact(s): Ipsen Clinical Study Enquiries - clinical.trials@ipsen.com

Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT06016842