

A Study to Assess How Well and Safely Elafibranor Works in Adult Participants With Primary Sclerosing Cholangitis

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 75 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Adults participants aged 18 years or older * Confirmed diagnosis of primary sclerosing cholangitis based on standard clinical, biochemical, and imaging criteria * Compensated liver disease at screening * Stable background therapy, where applicable prior to study entry * Women of childbearing potential have to apply during the entire duration of the study a highly effective method of birth control * Ability to provide written informed consent and comply with study procedures.

Exclusion Criteria:

\- History or presence of other concomitant chronic liver disease \- History of hepatic decompensation, including: i) History of liver transplantation, current MELD 3.0 score ≥ 12 due to hepatic impairment. ii) Evidence of complications of cirrhosis * Participants with cirrhosis who are also classified as Child-Pugh B or C based on the Child Pugh score. * History of biliary intervention within 60 days prior to the screening period, and/or presence of percutaneous drain or bile duct stent at SV. * History of bacterial cholangitis, and/or participant on antibiotics for prophylaxis of recurrent cholangitis within 60 days prior to the SV. * History or any current suspicion of cholangiocarcinoma or 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. * Medical conditions that may cause non-hepatic increases in ALP (e.g. Paget's disease). * Administration of the following medications are prohibited as specified below: i) 3 months prior to baseline: norcholeic acid, fibrates, seladelpar and glitazones. ii) 3 months prior to baseline: cyclosporine, mycophenolate, pentoxifylline, and chronic systemic corticosteroids (except as part of management of IBD at an ongoing stable dose); 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 or medical device study containing active substance within 30 days or five half-lives, whichever is longer, prior to the SV.

*Participants with previous exposure to elafibranor. * 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. * Significant renal disease, * For female participants: known pregnancy, or has a positive serum pregnancy test, or lactating. * Regular alcohol intake in excess of the recommended limit of 2 standard drinks per day for men or 1 standard drink per day for women * History of alcohol abuse, or other substance abuse within 1 year prior to SV. * Sensitivity to any of the study interventions, or components thereof, or drug or other allergy that contraindicates participation in the study. * Mental instability or incompetence * Participant has or is known to have tested positive for human immunodeficiency virus (HIV) type 1 or 2 at SV. * Medical conditions that may diminish life expectancy to < 2 years.

Conditions & Interventions

Interventions:

DRUG: Elafibranor, OTHER: Placebo

Conditions:

Primary Sclerosing Cholangitis

More Information

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

Principal Investigator:

IRB

Number:

System ID: NCT07387549

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