Phase 2a Evaluation of Safety, Tolerability, and Pharmacokinetics of PLN-74809 in Patients With Primary Sclerosing Cholangitis (PSC)

Status: Recruiting

Eligibility Criteria

Age: 18 years to 75 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

• Established clinical diagnosis of large duct PSC based on an abnormal cholangiography as assessed by magnetic resonance cholangiopancreatography (MRCP), endoscopic retrograde cholangiopancreatography (ERCP), and/or percutaneous transhepatic cholangiopancreatography (PTC) in the context of cholestatic liver chemistry

• Suspected liver fibrosis, as defined by liver stiffness measurement (LSM), assessed by ultrasound-based transient elastography (TE, FibroScan®) OR Enhanced Liver Fibrosis (ELF) Score OR Historical liver biopsy showing fibrosis without cirrhosis (by any scoring system) OR Magnetic resonance elastography (MRE)

• Serum ALP concentration within normal limits or > 1 times the upper limit of normal (ULN)

• Participants receiving treatment for IBD are allowed, if on a stable dose from screening and expected to remain stable for the duration of the study

• Serum AST and ALT concentration ≤ 5 times the upper limit of normal

• If receiving treatment with UDCA, therapy is at a dose of < 25 mg/kg/day, has been stable for at least 3 months before screening.

Exclusion Criteria:

• Other causes of liver disease, including secondary sclerosing cholangitis or viral, metabolic, or alcoholic liver disease, as assessed clinically

• Known or suspected overlapping clinical and histologic diagnosis of autoimmune hepatitis

• Small duct PSC with no evidence of large duct involvement (evidence of PSC on historical liver histology, with normal bile ducts on cholangiography)

• Presence of liver cirrhosis as assessed by liver histology, ultrasound-based liver stiffness measurement, ELF score, MRE, and/or signs and symptoms of hepatic decompensation (including but not limited to, jaundice, ascites, variceal hemorrhage, and/or hepatic encephalopathy.

• Serum ALP concentration > 10 times the upper limit of normal.

Conditions & Interventions

Interventions:
Drug: PLN-74809, Drug: Placebo
Conditions:
Primary Sclerosing Cholangitis

More Information

Contact(s): Pliant Therapeutics Medical Monitor - clintrials@pliantrx.com
Principal Investigator: Luketic, Velimir, A
Phase: Phase 2
IRB
Number: HM20019793
System ID: NCT04480840
