Reading Hospital
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Full Title	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety, Tolerability, and Efficacy of Cilofexor in Non-Cirrhotic Subjects with Primary Sclerosing Cholangitis
Principal Investigator	Eyob Feyssa, MD
Sub-Investigators	Andres Riera, MD Vishal Patel, MD
Study Objectives	To evaluate whether cilofexor (CILO, previously known as GS-9674) reduces the risk of fibrosis progression among non-cirrhotic subjects with PSC.

Inclusion Criteria

- Diagnosis of large duct PSC based on cholangiogram (magnetic resonance cholangiopancreatography [MRCP], endoscopic retrograde cholangiopancreatography [ERCP], or percutaneous transhepatic cholangiogram [PTC])
- Liver biopsy at Screening that is deemed acceptable for interpretation and demonstrates stage F0 – F3 fibrosis (according to the Ludwig classification) in the opinion of the central reader
- Subject has the following laboratory parameters at the Screening visit, as determined by the central laboratory:
  - Platelet count ≥ 150,000/mm3
  - Estimated glomerular filtration rate (eGFR) ≥ 30 milliliter/minute (mL/min), as calculated by the Cockcroft-Gault equation
  - ALT ≤ 8 x ULN
  - Total bilirubin < 2 mg/dL, unless the subject is known to have Gilbert's syndrome or hemolytic anemia
  - International normalized ratio (INR) ≤ 1.4, unless due to therapeutic anticoagulation
  - Negative anti-mitochondrial antibody

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- For subjects on ursodeoxycholic acid (UDCA), the dose of UDCA must have been stable in the opinion of the investigator for at least 6 months before Screening. For subjects not on UDCA, no UDCA use for at least 6 months prior to Screening

Exclusion Criteria

- Current or prior history of any of the following: cirrhosis, liver transplantation, cholangiocarcinoma or hepatocellular carcinoma, ascending cholangitis within 30 days of Screening
- Presence of a percutaneous drain or biliary stent
- Other causes of liver disease including IgG4-related sclerosing cholangitis, autoimmune hepatitis/PSC overlap syndrome, secondary sclerosing cholangitis, small duct PSC (histologic evidence of PSC with normal bile ducts on cholangiography), and viral, metabolic, alcoholic, and other autoimmune conditions
- Unstable cardiovascular disease, HIV infection, HBV infection, HCV infection, Current moderate to severely active inflammatory bowel disease (IBD), habitual alcohol consumption greater than 21 oz/week for males or 14 oz/week for females
- Use of antibiotics (e.g., vancomycin, metronidazole, minocycline, etc.) for the treatment of PSC within 60 days of Screening

Affiliations & Sponsors PRA, Gilead

Keywords Primary Sclerosing Cholangitis, PSC, cilofexor, fibrosis progression