A Study of CS0159 in Patients With PBC With Inadequate Response or Intolerance to UDCA

NCT07282353

Status	RECRUITING
Phase	Phase 3
Sponsor	Cascade Pharmaceuticals, Inc
Enrollment	135 participants

Key Eligibility Criteria

Inclusion (20)

- Must have given written informed consent (signed and dated) and any authorizations required by local law;
- When signing ICF age e18 years d75 years, male or female;
- Meets the diagnostic criteria of PBC, based on any two of the following criteria:
- History of ALP above 1.0× ULN for at least 6 months
- Positive antimitochondrial antibody (AMA) titer (\>1:40 on immunofluorescence or M2 positive by ELISA) or positive PBC- specific antinuclear antibody (ANA) (either SP100 or GP210 positive)

... and 15 more (see full listing online)

Exclusion (39)

- Previous exposure to CS0159;
- History of allergy to the CS0159 or its excipients or drugs of similar chemical classes;
- Advanced PBC as defined by the Rotterdam criteria (albumin\<1.0×LLN AND TB \>1.0× ULN);
- Patients who have had clinically significant complications of hepatic cirrhosis with clinically significant portal hypertension (CSPH), including the following:
- History of liver transplantation, current placement on a liver transplant list, current MELD -Na score e 12;

... and 34 more (see full listing online)

Locations (41 total)

The First Affiliated Hospital of USTC Anhui Provincial Hospital, Hefei, Anhui, China
The Second Affiliated Hospital of Anhui Medical University, Hefei, Anhui, China
Beijing Friendship Hospital, Capital Medical University, Beijing, Beijing Municipality, China
... and 38 more locations