Evaluate PK & Safety of Saroglitazar in Subjects With Moderate Hepatic Impairment Due to Cholestatic Liver Disease

NCT06825559

Status	RECRUITING
Phase	Phase 1
Sponsor	Zydus Therapeutics Inc.
Enrollment	6 participants

Key Eligibility Criteria

Inclusion (7)

- Male and/or female aged 18 to 80 years (both inclusive) at the time of signing the ICF.
- Body mass index within the range 18.0 to 48.0 kg/m2 (inclusive) at screening.
- Ability to swallow and retain oral medication.
- Subjects having documented history of hepatic impairment with cirrhosis due to cholestatic liver disease having Child-Pugh Turcotte score 7 to 9. If the hepatic impairment classification for the subject is not the same at screening and Day -1, enrolment of the subject into a hepatic category group will be at the discretion of the investigator.
- Laboratory test values must be clinically acceptable to the investigator and meet all the following parameters at screening:

... and 2 more (see full listing online)

Exclusion (17)

- Any significant or unstable medical condition or other instability that would prevent the subject from participating in the study as determined by the investigator
- History of malignancy of any type in the last 3 years of screening, with the exception of the following: in situ cervical or breast cancer or surgically excised non-melanoma skin cancers (i.e., basal cell or squamous cell carcinoma).
- History of stomach or intestinal surgery or resection within 6 months of screening that would potentially alter absorption and/or excretion of orally administered drugs (uncomplicated appendectomy, cholecystectomy, and hernia repair will be allowed).
- The history of any significant drug allergy (such as anaphylaxis) deemed clinically relevant by the investigator.
- Any major surgery within 3 months of screening.

... and 12 more (see full listing online)

Locations (1 total)

Zydus Site US001, Indianapolis, Indiana, United States