

Open-Label Extension Study of Saroglitazar Magnesium in Participants With Primary Biliary Cholangitis

NCT06427395

Status	RECRUITING
Phase	Phase 3
Sponsor	Zydus Therapeutics Inc.
Enrollment	150 participants

Key Eligibility Criteria

Inclusion (2)

- Must provide written informed consent and agree to comply with the trial protocol
- Participated and completed SARO.21.001, the double-blind treatment phase study

Exclusion (38)

- Consumption of 2 standard drinks per day if male and 1 standard drink per day if female for 3 consecutive months (12 consecutive weeks) throughout double-blind phase till screening.
 - Participants with MELD 3.0 score of 15 or greater
 - History or presence of other concomitant liver diseases at screening:
 - Chronic hepatitis B or C virus (HBV, HCV) infection
 - Primary sclerosing cholangitis (PSC)
- ... and 33 more (see full listing online)

Locations (28 total)

Zydus US013, Los Angeles, California, United States
Zydus US011, Pasadena, California, United States
Zydus US043, Sacramento, California, United States
... and 25 more locations