

# A Study to Evaluate Efficacy and Safety of an Investigational Drug Named Volixibat in Patients With Itching Caused by Primary Biliary Cholangitis

NCT05050136

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 2
<b>Sponsor</b>	Mirum Pharmaceuticals, Inc.
<b>Enrollment</b>	260 participants

## Key Eligibility Criteria

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### Inclusion (5)

- Provide signed informed consent at the screening visit as well as comply with all study visits and requirements through the end of the study
- Male or female, age ≥18 years at the screening visit
- Confirmed diagnosis of PBC in line with the AASLD guidelines
- UDCA, anti-pruritic medication and PPAR agonist use will be allowed if meeting additional criteria
- Qualified pruritus associated with PBC as assessed by Adult ItchRO

### Exclusion (6)

- Pruritus associated with an etiology other than PBC
  - Evidence or clinical suspicion of decompensated cirrhosis or a history of decompensation events
  - Current symptomatic cholelithiasis or inflammatory gallbladder disease
  - History of small bowel surgery/resection impacting the terminal ileum that may disrupt the enterohepatic circulation.
  - Evidence, history, or suspicion of other liver diseases; PBC patients with AIH are not excluded
- ... and 1 more (see full listing online)

## Locations (130 total)

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Southern California Research Center, Coronado, California, United States  
Cedars Sinai Medical Center, Los Angeles, California, United States  
University of California Los Angeles, Los Angeles, California, United States  
... and 127 more locations