Long-Term Low-Intervention SafEty and Clinical Outcomes Clinical Study of LivmArli® in Patients With Alagille Syndrome in the European Union (LEAP-EU)

NCT07290257

Status	RECRUITING
Phase	Phase 4
Sponsor	Mirum Pharmaceuticals, Inc.
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (5)

- Informed consent and assent (as applicable)
- e2months of age at Day 1
- A clinically and/or genetically confirmed ALGS diagnosis with pruritus secondary to chronic cholestasis
- For the primary cohort, prescribed Livmarli at time of study entry
- For the supplemental cohort, prescribed Livmarli prior to study entry

Exclusion (5)

- History of Liver Transplant
- Any contraindications against Livmarli (as per SmPC)
- Any condition or abnormality that, in the opinion of the investigator, may interfere with the participation in or completion of the study
- Received an investigational drug within 30 days before the first dose of Livmarli (Participation in previous maralixibat studies or expanded-access programs is acceptable.)
- Baseline data before start of treatment of Livmarli are unavailable (\<2 values before treatment) for key safety (LFTs, FSV laboratory results) and key efficacy (sBA, pruritus) parameter

Locations (13 total)

Cliniques Universitaires Saint Luc (UCLouvain), Brussels, Belgium
University Hospital Gent (UZ Gent), Ghent, Belgium
Hospices Civils de Lyon - Hopital Femme Mère Enfant, Bron, Auvergne-Rhône-Alpes, France
... and 10 more locations