Long-term Safety and Efficacy of Odevixibat in Patients With Alagille Syndrome

NCT05035030

Status	RECRUITING
Phase	Phase 3
Sponsor	Albireo, an Ipsen Company
Enrollment	70 participants

Key Eligibility Criteria

Inclusion (10)

- Cohort 1 :
- Completion of the 24-week Treatment Period of Study A4250-012
- Signed informed consent and assent as appropriate. Patients who turn 18 years of age (or legal age per country) during the study will be required to re-consent to remain on the study
- Caregivers (and age-appropriate patients) must be willing and able to use an electronic diary (eDiary) device as required by the study
- Sexually active males and females must agree to use a reliable contraceptive method with d1% failure rate (such as hormonal contraception, intra-uterine device, or complete abstinence) from signed informed consent through 90 days after last dose of study drug.

... and 5 more (see full listing online)

Exclusion (28)

- Cohort 1 :
- Decompensated liver disease, history or presence of clinically significant ascites, variceal hemorrhage, and/or encephalopathy
- Patients who were not compliant with study drug treatment or procedures in Study A4250-012
- Any other conditions or abnormalities which, in the opinion of the investigator, may compromise the safety of the patient, or interfere with the patient participating in or completing the study
- Known hypersensitivity to any components of odevixibat

... and 23 more (see full listing online)

Locations (35 total)

Rady Children's Hospital, San Diego, California, United States
UCSF, San Francisco, California, United States
Children's Healthcare of Atlanta, Atlanta, Georgia, United States
... and 32 more locations