

The Efficacy and Safety of Rilzabrutinib in Patients Aged 10 to 65 Years With Sickle-cell Disease

NCT06975865

Status	RECRUITING
Phase	Phase 3
Sponsor	Sanofi
Enrollment	192 participants

Key Eligibility Criteria

Inclusion (6)

- Participants who have been diagnosed with SCD.
- Participants who have had between e2 to d10 episodes of documented acute clinical VOC within 12 months of the screening visit.
- Participants who are either not on hydroxyurea and/or L-glutamine at the Screening Visit and does not plan to receive them during the course of the study or has received HU and/or L-glutamine for a minimum of 6 months. Participants on hydroxyurea and/or L-glutamine must have been on a stable weight-based dose level (mg/kg) for at least 3 months prior to the Screening Visit, with the intent to continue at the same weight-based dose level for the duration of the study, except for safety reasons.
- Participants with Eastern Cooperative Oncology Group (ECOG) performance status grade 2 or lower.
- Contraceptive use by men and women should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies.

... and 1 more (see full listing online)

Exclusion (9)

- Participants are excluded from the study if any of the following criteria apply: Participants with medical history of lymphoma, leukemia, or any malignancy within the past 5 years except for basal cell or squamous epithelial carcinomas of the skin that have been resected with no evidence of metastatic disease for the past 3 years.
- Clinically relevant cardiac abnormality, in the opinion of the Investigator or electrocardiogram (ECG) findings.
- Participants with history of stroke, or history of abnormal transcranial doppler.
- Participants with uncontrolled or active HBV infection and/or HCV infection including those receiving antiviral therapy at the time of screening.
- HIV infection.

... and 4 more (see full listing online)

Locations (53 total)

University of Alabama at Birmingham- Site Number : 8400003, Birmingham, Alabama, United States

Phoenix Children's Hospital- Site Number : 8400028, Phoenix, Arizona, United States

University of California San Francisco- Site Number : 8400040, Fresno, California, United States

... and 50 more locations