Safety, Efficacy, and Pharmacokinetics of CSL889 in Adults and Adolescents With Sickle Cell Disease During Vaso-Occlusive Crisis

NCT06699849

Status	RECRUITING
Phase	Phase 2
Sponsor	CSL Behring
Enrollment	70 participants

Key Eligibility Criteria

Inclusion (5)

- At the time of informed consent:
- years of age (adults); or
- to less than (\<) 18 years of age (adolescents, where approved and when enrollment for adolescents has been opened by the sponsor, with the endorsement of the Independent Data Monitoring Committee \[IDMC\])
- Diagnosed with SCD (any genotype).
- Presented at the study site with a new acute VOC necessitating treatment with parenteral opioids.

Exclusion (3)

- VOC pain onset greater than (\>) 72 hours before administration of first parenteral opioid.
- Must not have a history of \> 5 VOCs requiring hospital admission in the past 6 months; or signs and / or symptoms of ACS; or new neurological symptoms suggestive of acute stroke or transient ischemic attack; or any stage (acute kidney injury) AKI; or been discharged from inpatient hospital admission for VOC or other vaso-occlusive event within 14 days before the current presentation.
- Serum hemoglobin \< 6 g/dL, serum ferritin e 2000 ng/mL, receiving an approved medication for SCD that has not been on a stable, well-tolerated regimen, currently taking methadone or buprenorphine.

Locations (15 total)

University of California Irvine, Orange, California, United States
Golisano Children's Hospital, Fort Myers, Florida, United States
The Foundation for Sickle Cell Disease, Hollywood, Florida, United States
... and 12 more locations