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

Status: RECRUITING

Eligibility Criteria

Age: 12 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* At the time of informed consent: * 18 years of age (adults); or * 12 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 Criteria:

* 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 ≥ 2000 ng/mL, receiving an approved medication for SCD that has not been on a stable, well-tolerated regimen, currently taking methadone or buprenorphine.

Conditions & Interventions

Interventions:
BIOLOGICAL: CSL889, DRUG: Placebo
Conditions:
Sickle Cell Disease Vaso-occlusive Crisis
Keywords:
Sickle cell disease, Acute kidney injury, Pharmacokinetics, Acute chest syndrome, Vaso-occlusive crisis, Hemopexin

More Information

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