A Dose-Finding Study of Tebapivat to Assess Efficacy, and Safety in Participants With Sickle Cell Disease (SCD)

NCT06924970

Status	RECRUITING
Phase	Phase 2
Sponsor	Agios Pharmaceuticals, Inc.
Enrollment	56 participants

Key Eligibility Criteria

Inclusion (3)

- Documented diagnosis of SCD (HbSS, HbSC \[combined heterozygosity for hemoglobins S and C\], sickle hemoglobin \[HbS\]/²0thalassemia, HbS/²+thalassemia, or other sickle cell syndrome variants).
- Hemoglobin e5.5 and d10.5 grams per decilitre (g/dL). Hemoglobin concentration must be based on an average of at least 2 Hb concentration measurements (separated by e7 days) collected during the screening period.
- If taking hydroxyurea, the hydroxyurea dose must be stable for at least 90 days before randomization. Discontinuation of hydroxyurea requires a 90-day washout before providing informed consent.

Exclusion (8)

- Receiving regularly scheduled red blood cell (RBC) transfusion therapy (also termed chronic, prophylactic, or preventative transfusion); episodic transfusion in response to worsened anemia or vaso-occlusive crisis (VOC) is permitted. Additionally, a participant who requires episodic transfusion(s) may not have received a transfusion(s) within 60 days before providing informed consent or during the screening period.
- \>10 sickle cell pain crisis (SCPCs) in the 12 months before providing informed consent.
- Receiving anabolic steroids that have not been stopped for at least 4 weeks before randomization. Testosterone replacement therapy to treat hypogonadism is allowed; the testosterone dose and preparation must be stable for e10 weeks before randomization.
- Hospitalized for an SCPC and/or other vaso-occlusive event within 14 days before providing informed consent or within 14 days before randomization. If an SCPC occurs during the screening period, the screening period may be extended with Medical Monitor approval.
- Receiving treatment with voxelotor, crizanlizumab, or L-glutamine within 90 days before randomization.

... and 3 more (see full listing online)

Locations (32 total)

UCHealth at University of Colorado Anschutz Medical Campus, Aurora, Colorado, United States
UConn Health, Farmington, Connecticut, United States
Children's National Hospital, Washington D.C., District of Columbia, United States
... and 29 more locations