A Study to Investigate the Efficacy and Safety of Crizanlizumab (5 mg/kg) Compared With Placebo in Adolescent and Adult Sickle Cell Disease Patients Who Experience Frequent Vaso-Occlusive Crises (SPARKLE)

Last Update: Apr 22, 2025

A Phase III, Multicenter, Randomized, Placebo Controlled, Double-blind Study to Assess Efficacy and Safety of Crizanlizumab (5 mg/kg) Versus Placebo, With or Without Hydroxyurea/Hydroxycarbamide Therapy, in Adolescent and Adult Sickle Cell Disease Patients With Frequent Vaso-Occlusive Crises

ClinicalTrials.gov Identifier:
NCT06439082

Novartis Reference Number:CSEG101A2303

See if you Pre-qualify

All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

A phase III, multi-center, randomized, placebo-controlled, double-blind study to assess efficacy and safety of crizanlizumab (5 mg/kg) versus placebo, with or without hydroxyurea/hydroxycarbamide therapy, in adolescent and adult Sickle Cell Disease patients with frequent vaso-occlusive crises. Study CSEG101A2303 (SPARKLE) is a Phase III, multicenter, randomized, double-blind study to assess efficacy and safety of crizanlizumab 5 mg/kg versus placebo, with or without hydroxyurea/ hydroxycarbamide therapy (HU/HC), in Sickle Cell Disease patients aged 12 years and older with frequent vaso-occlusive crises (4-12 events in 12 months prior to the screening visit).

Participants will be randomized in a 2:1 ratio to the crizanlizumab 5 mg/kg or placebo treatment arm. Central randomization will be stratified by concomitant HU/HC usage (yes/no) and region (South America, North America, and sub-Saharan Africa) at baseline.

Condition
Sickle Cell Disease
Phase
Phase3
Overall Status
Recruiting
Number of Participants
315
Start Date
Oct 24, 2024

Completion Date
Apr 19, 2030
Gender
All
Age(s)
12 Years - 100 Years (Child, Adult, Older Adult)

Interventions

Biological

Crizanlizumab

Crizanlizumab is supplied in single use 10 mL glass vials at a concentration of 10 mg/mL. One vial contains 100 mg of crizanlizumab. This is a concentrate for solution for IV infusion.
Drug

Placebo

Placebo is supplied in single use 10 mL glass vials at a concentration of 0 mg/mL. This is a concentrate for solution for IV infusion.

Eligibility Criteria

Key Inclusion Criteria:

1. Participants must be aged 12 years and older on the day of signing informed consent. Adolescents include participants aged 12 to \<18 years old and adults include participants aged 18 years and older.
2. Confirmed diagnosis of SCD by Hb electrophoresis or high-performance liquid chromatography (HPLC) (performed locally or by central laboratory if not available locally). All SCD genotypes are eligible.
3. Experienced 4 to 12 VOCs (refer to Section 8.3.1 for study definition of VOC) that are HCP-managed (including VOCs leading to management at a health care facility or those managed via remote consultation) within the 12 months prior to the screening visit. Baseline VOCs are determined by medical history and are required to be documented at source.
4. If the participant is on HU/HC, they must be taking it for at least 6 months and at stable dose for at least 3 months prior to the Screening visit and plan to continue taking it at the same dose and schedule until at least the participant has reached 52 weeks of the planned study treatment. Participants who have initiated HU/HC 6-12 months prior to the screening visit must have evidence of insufficient control of acute pain despite initiation. These participants must have a cumulative of 4-12 VOCs in the 12 months prior to the screening period, with at least 2 during the last 6 months while on HU/HC. If receiving erythropoietin stimulating agent, the participant must have been receiving the drug for at least 6 months prior to screening visit and plan to continue taking the drug at the same dose and schedule until the participant has reached 52 weeks of the planned study treatment.

Participants who have not been receiving HU/HC, and/or erythropoietin stimulating agent must not have received it for at least 6 months prior to screening visit.

Key Exclusion Criteria:

1. Fewer than 4 or more than 12 VOCs that are HCP-managed (including VOCs leading to management at a

health care facility or those managed via remote consultation) within the 12 months prior to screening visit as determined by medical history and documented at source.
2. History of stem cell transplant and/or gene therapy.
3. Received blood products within 30 days prior to Week 1 Day 1 dosing.
4. Any documented history of a clinical stroke or intracranial hemorrhage, or an uninvestigated neurologic finding within the past 12 months before screening visit. Silent infarct only present on imaging is not excluded.
5. Participating in a chronic transfusion program (pre-planned series of transfusions for prophylactic purposes) and/or planning to undergo an exchange transfusion during the duration of the study; episodic transfusion in response to worsened anemia or VOC is permitted.
6. Contraindication or hypersensitivity to any drug or metabolites from similar class as study drug or to any excipients of the study drug formulation. History of severe hypersensitivity reaction to other monoclonal antibodies, which in the opinion of the investigator may pose an increased risk of serious infusion reaction.

Colombia

Novartis Investigative Site

Recruiting

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Novartis Investigative Site

Recruiting

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