Rollover Study for Patients With Sickle Cell Disease Who Have Completed a Prior Novartis-Sponsored Crizanlizumab Study

Last Update: Jul 03, 2025
An Open-label, Multi-center, Phase IV, Rollover Study for Patients With Sickle Cell Disease Who Have Completed a Prior Novartis-Sponsored Crizanlizumab Study
ClinicalTrials.gov Identifier:
NCT04657822
Novartis Reference Number:CSEG101A2401B
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

This is a multi-center multi-national rollover study to allow continued access to crizanlizumab for patients with sickle cell disease (SCD) who are on crizanlizumab treatment in a Novartis-sponsored study (parent study) and are benefiting from the treatment as judged by the investigator. There will be no screening period for this study as patients will transfer directly from parent studies. After providing informed consent, all eligible participants should start Crizanlizumab treatment at the earliest convenience following the treatment schedule of 28 days of the last dose in the parent study. Crizanlizumab will be administered at the same dose/schedule as in the parent study.

Study participants will have a safety follow up visit conducted 105 days after last administration of study treatment. The safety follow up at 105 days is not applicable for those participants who continue to receive Crizanlizumab after end of treatment visit either commercially or through PSDS.

The study is expected to remain open for 10 years from the first Patient's first visit (FPFV) in this clinical study or until study treatment becomes commercially available and is reimbursed in the respective indication or until such time that all enrolled patients no longer need treatment with Crizanlizumab, or a PSDS treatment plan is allowed and approved as per local laws and regulations, whichever comes first

Condition
Sickle Cell Disease
Phase
Phase4
Overall Status
Recruiting
Number of Participants
130
Start Date
Jun 10, 2021

Completion Date
Jun 10, 2031
Gender
All
Age(s)
6 Years - 100 Years (Child, Adult, Older Adult)

Interventions

Drug

Crizanlizumab

Concentrate for solution for infusion for Intravenous use

Eligibility Criteria

Inclusion Criteria:

1. Written informed consent/assent, according to local guidelines, signed by the adult patients. In the population under 18 years, it will be signed by the patient and/or by the parents or legal guardian prior to enrolling in the rollover study and receiving study medication
2. SCD patient currently enrolled in a Novartis-sponsored study receiving crizanlizumab and has fulfilled all the requirements in the parent study. Patient is currently benefiting from the treatment with crizanlizumab as determined by the investigator and has completed the treatment schedule as planned in the parent study
3. Patient has demonstrated compliance to the planned visit schedule in the parent study, and in the opinion of the investigator has shown willingness and ability to comply with future visit schedules

Exclusion Criteria:

1. Patient had permanently discontinued from crizanlizumab study treatment in the parent study before the parent study completion
2. Ongoing/unresolved treatment-related Grade 3 or higher AEs, and/or any ongoing AE requiring dose interruption. Patients meeting all other eligibility criteria may be enrolled once toxicities have resolved unless those toxicities were grade 4
3. Concurrent participation in any other investigational clinical trial other than the parent study or plan to participate in any other investigational clinical trial
4. Pregnant or nursing women
5. Women of childbearing potential who are unwilling to be on highly effective contraceptives during dosing and until 15 weeks after stopping treatment with crizanlizumab
6. SCD patients who do not meet parent study protocol criteria to continue with crizanlizumab

Belgium

Novartis Investigative Site

Recruiting

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If the location of your choosing does not feature any contact detail, please reach out using the information below.

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct04657822*

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