The Efficacy and Safety of Rilzabrutinib in Patients Aged 10 to 65 Years With Sickle-cell Disease

Status: RECRUITING

Eligibility Criteria

Age: 10 years to 65 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Participants who have been diagnosed with SCD. * Participants who have had between ≥2 to ≤10 episodes of documented acute clinical VOC within 12 months of the screening visit. * Participants who are either not on hydroxyurea and/or L-glutamine at the Screening Visit and does not plan to receive them during the course of the study or has received HU and/or L-glutamine for a minimum of 6 months. Participants on hydroxyurea and/or L-glutamine must have been on a stable weight-based dose level (mg/kg) for at least 3 months prior to the Screening Visit, with the intent to continue at the same weight-based dose level for the duration of the study, except for safety reasons. * Participants with Eastern Cooperative Oncology Group (ECOG) performance status grade 2 or lower. * Contraceptive use by men and women should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies. * For participants ≥10 to \<18 years of age: the parent(s)/legal guardian(s) must provide written informed consent prior to any study-related procedures being performed.

Exclusion Criteria:

* Participants are excluded from the study if any of the following criteria apply: Participants with medical history of lymphoma, leukemia, or any malignancy within the past 5 years except for basal cell or squamous epithelial carcinomas of the skin that have been resected with no evidence of metastatic disease for the past 3 years. * Clinically relevant cardiac abnormality, in the opinion of the Investigator or electrocardiogram (ECG) findings. * Participants with history of stroke, or history of abnormal transcranial doppler. * Participants with uncontrolled or active HBV infection and/or HCV infection including those receiving antiviral therapy at the time of screening. * HIV infection. * A history of active or latent tuberculosis (TB) * Positive COVID-19 molecular test. * Participant is taking or has received crizanlizumab (ADAKVEO®) within 90 days and/or voxelotor (OXBRYTA®) within 30 days prior to the Screening visit. The above information is not intended to contain all considerations relevant to a patient's potential participation in a clinical trial.

Conditions & Interventions

Interventions:
DRUG: Rilzabrutinib, DRUG: Placebo
Conditions:
Sickle Cell Disease

More Information

Contact(s): Trial Transparency email recommended (Toll free for US & Canada) - contact-us@sanofi.com
Principal Investigator:
IRB
Number:
System ID: NCT06975865
