A Study to Evaluate How Well Etavopivat Works in People With Sickle Cell Disease

NCT06612268

Status	RECRUITING
Phase	Phase 3
Sponsor	Novo Nordisk A/S
Enrollment	408 participants

Key Eligibility Criteria

Inclusion (5)

- Male or female.
- Age 12 years or above at the time of signing the informed consent.
- Confirmed diagnosis of sickle cell disease: Documentation of sickle cell disease (SCD) genotype (HbSS, HbS²0thalassemia or other sickle cell syndrome variants) based on prior history of laboratory testing or screening test results from central laboratory. Molecular genotyping is not required. SCD genotype may be determined from the results of haemoglobin (Hb) electrophoresis, high-performance liquid chromatography (HPLC) or similar testing. Note that Hb electrophoresis is performed by the central laboratory at screening.
- Have 1-15 episodes of documented vaso occlusive crises (VOC) within the 12 months prior to screening. Documentation must exist in the participant's medical record prior to randomisation. Events based solely on participant recall without supporting documentation should not be counted towards eligibility.
- Hb greater than or equal to (e) 5.0 and less than or equal to (d) 10.0 g/dL (greater than or equal to (e) 50 and less than or equal to (d) 100 g/L) at screening.

Exclusion (14)

- More than 15 VOCs within the past 12 months prior to screening documented in the participant's medical record. Events based solely on participant recall without supporting documentation should not be counted towards eligibility.
- Use of voxelotor or similar agent within 28 days prior to starting study treatment or anticipated need for this agent during the study.
- Use of a selectin antagonist (e.g., crizanlizumab, monoclonal antibody or small molecule) within 28 days or 5 half-lives (whichever is longer) prior to starting study treatment or anticipated need for such agents during the study.
- Receiving regularly scheduled blood (RBC) transfusion therapy (also termed chronic, prophylactic, or preventive transfusion) or greater than or equal to 6 transfusion events in the previous 12 months (i.e., an average of 1 transfusion event every 60 days).
- Participants who have received an RBC transfusion for any reason within 60 days of the screening period or 60 days of the randomisation day are only eligible if HbA (adult haemoglobin) less than 10% by Hb electrophoresis is documented prior to starting study treatment.

... and 9 more (see full listing online)

Locations (172 total)

Uni of Alabama at Birmingham, Birmingham, Alabama, United States
Univer South Alabama Ped/Onc, Mobile, Alabama, United States
Phoenix Children's Hsptl, Phoenix, Arizona, United States
... and 169 more locations