

A Research Study Looking at Long-term Treatment With Etavopivat in People With Sickle Cell Disease or Thalassaemia

NCT06609226

Status	RECRUITING
Phase	Phase 3
Sponsor	Novo Nordisk A/S
Enrollment	480 participants

Key Eligibility Criteria

Inclusion (4)

- Participant must have ongoing participation in an etavopivat parent study for treatment of sickle cell disease (SCD) or thalassaemia and have completed at least a treatment period of the parent study.
- Participant must have derived clinical benefit from treatment with etavopivat, as determined by the investigator.
- Any participant with dose reduction or temporary discontinuation will need to be successfully rechallenged to the full dose of etavopivat before transferring.
- Participants on hydroxyurea (HU), crizanlizumab or l-glutamine oral powder (Endari®) treatment at the time of consent may be eligible if they have been on a stable dose in the parent study as defined at the investigator's discretion. Necessary adjustments related to weight or age are accepted. Participants with temporary dose reductions or pauses due to medical reasons may still be considered to have a stable dose, as determined by the investigator, who will assess the impact of these adjustments based on clinical context and the participant's overall health status.

Exclusion (9)

- Any disorder, except for conditions associated with SCD or thalassaemia, which in the investigator's opinion might jeopardise participant's safety or compliance with the protocol.
- Participant withdrew or had permanent treatment discontinuation from an etavopivat clinical study.
- Participants on permanent dose reduction (greater than > 28 days or more) or ongoing temporary treatment discontinuation.
- Use of any of the following within the timeframes prior to the transfer visit as stated:
- Use of haemoglobin S (HbS) polymerisation inhibitors within participation of the parent study or anticipated need for this agent during this study.

... and 4 more (see full listing online)

Locations (103 total)

Univ of Alabama Birmingham, Birmingham, Alabama, United States
Phoenix Children's Hsptl, Phoenix, Arizona, United States
Children's Hospital Los Angeles - Endocrinology, Los Angeles, California, United States
... and 100 more locations

<https://clinicaltrials.gov/study/NCT06609226>

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