

# Single-dose Pharmacokinetics of Pociredir in Participants With Sickle Cell Disease

NCT07431398

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Status	RECRUITING
Phase	Phase 1
Sponsor	Fulcrum Therapeutics
Enrollment	24 participants

## Key Eligibility Criteria

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### Inclusion (7)

- Documented SCD at the time of screening, as confirmed through review of medical records or high-performance liquid chromatography (HPLC)/electrophoresis.
  - Participant, who if female and of childbearing potential, agrees to use 2 effective methods of contraception, one which must be highly effective, or practice abstinence starting at the time of the ICF signing to 90 days after the last dose of study drug, and, who if male, agrees to use condoms or practice abstinence from the time of ICF signing to 90 days after the last dose of study drug.
  - Total Hb e 5.5 grams/deciliter (g/dL) and d 12 g/dL (males) or d 10.6 g/dL (females) at screening
  - Participant must meet all of the following laboratory values at screening:
  - Absolute neutrophil count e  $1.5 \times 10^9/L$  (cells/liter)
- ... and 2 more (see full listing online)

### Exclusion (7)

- Participant has had any of the following in the 14 days prior to dosing: major surgery, serious illness, infection (clinically significant bacterial, fungal, parasitic or viral infection which requires therapy), fever not resolved within 3 days and requiring treatment, or sickle cell complication requiring care from a medical provider in a hospital or emergency care setting.
  - Participant has a serious medical condition other than SCD that, in the opinion of the Investigator, would preclude them from participating in the study, or which is unresolved or requiring ongoing treatment.
  - Elective surgery planned for the time period of the study.
  - Use of any medications that induce or inhibit cytochrome P450 (CYP) 3A4, inhibit P-glycoprotein, breast cancer resistance protein, or multidrug and toxin extrusion protein 2-K, or are substrates of CYP2B6 within 14 days prior to first dose of study drug or anticipated need for any of these medications during the study.
  - Participation in any other study with an investigational agent within the past 30 days or 5 half-lives, whichever is longer, prior to the first dose of study drug.
- ... and 2 more (see full listing online)

## Locations (6 total)

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Advanced Pharma - Miami, Miami, Florida, United States  
Omega Research Group, Orlando, Florida, United States  
Sonar Clinical Research, Riverdale, Georgia, United States  
... and 3 more locations

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<https://clinicaltrials.gov/study/NCT07431398>

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