MK-7075 (Miransertib) in Proteus Syndrome

NCT04316546

Status	RECRUITING
Phase	Phase 2
Sponsor	National Human Genome Research Institute (NHGRI)
Enrollment	45 participants

Key Eligibility Criteria

Inclusion (36)

- All participants in all Cohorts must meet the criteria below:
- Signed informed consent, and when applicable, signed assent
- Have a molecular diagnosis of Proteus syndrome with documented somatic AKT1 mutation from a CLIA-certified laboratory or international equivalent.
- Have progressive and measurable disease (e.g., a measurable manifestation of Proteus syndrome with evidence or report of worsening of manifestation(s)/ in the last 12 months)
- Adequate organ function as indicated by the following laboratory values:

... and 31 more (see full listing online)

Exclusion (17)

- An individual who meets any of the following criteria will be excluded from participation in this study:
- \- History of Type 1 or Type 2 uncontrolled diabetes mellitus requiring regular medication (other than metformin or other oral hypoglycemic agents) or fasting glucose greater than or equal to 160 mg/dL (if \>12 years old) and greater than or equal to 180 mg/dL (if less than or equal to 12 years old) at the baseline/screening visit
- History of clinically significant cardiac disorders:
- Myocardial infarction (MI) or congestive heart failure defined as Class II-IV per the New York Heart Association (NYHA) classification within six months of the first dose of miransertib (MI occurring \>6 months of the first dose of miransertib will be permitted)
- Grade 2 (per National Cancer Institute \[NCI\] Common Terminology Criteria for Adverse Events \[CTCAE v 5.0\]) or worse conduction defect (e.g., right or left bundle branch block).

... and 12 more (see full listing online)

Locations (1 total)

National Institutes of Health Clinical Center, Bethesda, Maryland, United States