

A Phase 2 Study of Mutant-selective PI3K Inhibitor, RLY-2608, in Adults and Children With PIK3CA Related Overgrowth Spectrum and Malformations Driven by PIK3CA Mutation

NCT06789913

Status	RECRUITING
Phase	Phase 2
Sponsor	Relay Therapeutics, Inc.
Enrollment	277 participants

Key Eligibility Criteria

Inclusion (4)

- The participant must have a clinical diagnosis of PROS or a malformation within the ISSVA classification.
- One or more documented activating PIK3CA mutation(s) that are targeted by selective PI3K inhibitors in lesional tissue and/or cell-free DNA from the lesion or blood. Some participants may be eligible without a documented PIK3CA mutation as long as no other genetic driver has been documented.
- Lansky (<16 yo) or Karnofsky (≥16 yo) performance status of e50.
- Agree to provide archived lesional fluid and/or tissue or be willing to undergo pretreatment lesional biopsy (if considered safe and medically feasible) to assess PIK3CA status.

Exclusion (6)

- History of hypersensitivity to PI3K inhibitors.
- Any factors that increase the risk of QTc prolongation or risk of arrhythmic events
- Clinically significant, uncontrolled cardiovascular disease
- Received disease-directed therapy prior to the first dose of study drug:
- Systemic therapy or antibody within 5 half-lives of the therapy.

... and 1 more (see full listing online)

Locations (25 total)

Phoenix Children's Hospital, Phoenix, Arizona, United States
Arkansas Children's Hospital, Little Rock, Arkansas, United States
University of California, Los Angeles, Los Angeles, California, United States
... and 22 more locations

<https://clinicaltrials.gov/study/NCT06789913>

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