

# Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of CYH33 in Patients With PIK3CA-related Overgrowth Spectrum (PROS) and PIK3CA-related Vascular Malformations (PRVM)

NCT06975618

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Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Haihe Biopharma Co., Ltd.
Enrollment	141 participants

## Key Eligibility Criteria

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### Inclusion (4)

- The patient or the patient's legal guardian (if applicable) voluntarily signs the Informed Consent Form.
- At the time of signing the informed consent, adult patients should be ≥18 years old (or meet the legal adult age according to local regulations), and adolescent patients should be ≥12 years old and <18 years old (or meet the legal definition of adolescent according to local regulations; additionally, adolescent patients should weigh ≥35 kg).
- The patient is diagnosed with PIK3CA-related overgrowth spectrum (PROS) or PIK3CA-related vascular malformations (PRVM), and provides a report confirming PIK3CA mutation detected by local laboratory or the Sponsor-designated central laboratory, with at least one measurable lesion related to PROS or PRVM.
- Patients should demonstrate adequate organ and bone marrow function during the 28-day screening period.

### Exclusion (3)

- PROS patients presenting solely with isolated macrodactyly, epidermal nevi/nevus, and megalencephaly (only one clinical feature or any combination of these three features) without other PROS-related lesions.
- Patients who have received any systemic treatment for PROS or PRVM within 8 weeks prior to the first dose of study drug, or any drug treatment for PROS or PRVM (e.g., mTOR inhibitors) within 28 days prior to the first dose of study drug.
- Patients who have previously received any PI3K inhibitor treatment.

## Locations (4 total)

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Capital Institute of Pediatrics, Beijing, Beijing Municipality, China  
Plastic Surgery Hospital, Chinese Academy of Medical Sciences, Beijing, Beijing Municipality, China  
Shanghai Ninth People Hospital, Shanghai Jiaotong University School of Medicine, Shanghai, Shanghai Municipality, China  
... and 1 more locations