

# A Phase Ib, Multicenter, Open-Label Study of Multiple-Dose EA5 in Adults With Paroxysmal Nocturnal Hemoglobinuria (PNH)

NCT07256301

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Status	RECRUITING
Phase	Phase 1
Sponsor	Shanghai Lanyi Therapeutics Co., Ltd.
Enrollment	24 participants

## Key Eligibility Criteria

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### Inclusion (15)

- Male or female subjects aged ≥18 years.
  - Body weight between 40 kg and 100 kg (inclusive) at screening.
  - Patients diagnosed with PNH, confirmed by flow cytometry demonstrating a PNH clone size (glycosylphosphatidylinositol-anchored protein-deficient granulocytes or monocytes) of ≥10% in peripheral blood, and meeting one of the following criteria:
    - a) Previously naive to complement inhibitor therapy; or
    - b) Previously treated with a complement inhibitor, which has been discontinued for ≥5 half-lives prior to screening.
- ... and 10 more (see full listing online)

### Exclusion (21)

- History of allogeneic bone marrow transplantation.
  - History of Neisseria meningitidis infection within 6 months prior to screening and before the first dose.
  - Known or suspected immunodeficiency (e.g., history of frequent or recurrent infections).
  - Known or suspected hereditary complement deficiency.
  - Evidence of active tuberculosis (TB) within 6 months prior to screening, or a history of active TB without having completed an appropriate, documented course of treatment; OR chest X-ray (posteroanterior and lateral) or CT scan findings during the 3 months prior to screening or during the screening period that suggest the presence of active TB infection.
- ... and 16 more (see full listing online)

## Locations (2 total)

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The Institute of Hematology & Blood Diseases Hospital (Chinese Academy of Medical Sciences), Tianjin, Tianjin Municipality, China  
The First Affiliated Hospital, Zhejiang University School of Medicine, Chengzhan Campus, Hangzhou, Zhejiang, China

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<https://clinicaltrials.gov/study/NCT07256301>

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