

# A Phase II Study Evaluating the Efficacy and Safety of XH-S003 Capsules in Patients With Paroxysmal Nocturnal Hemoglobinuria (PNH)

NCT06978699

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Status	RECRUITING
Phase	Phase 2
Sponsor	S-INFINITY Pharmaceuticals Co., Ltd
Enrollment	24 participants

## Key Eligibility Criteria

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### Inclusion (7)

- Male or female with aged  $\geq 18$  years old;
- Weight  $\geq 40$  kg and BMI  $\geq 18$  kg/m<sup>2</sup> ;
- Diagnosed with PNH: with red blood cell or granulocyte clone levels  $> 10\%$  detected by flow cytopy within 6 months prior to screening or during screening;
- Patients who have not previously received any complement inhibitor therapy;
- LDH  $> 1.5 \times \text{ULN}$  detected two times during the screening period (interval of 2 to 8 weeks);
- ... and 2 more (see full listing online)

### Exclusion (9)

- Subjects with laboratory evidence of bone marrow failure during the screening period (reticulocyte count  $< 100 \times 10^9/\text{L}$ , platelet count  $< 30 \times 10^9/\text{L}$ , or neutrophil count  $< 0.5 \times 10^9/\text{L}$ );
- Subjects receiving other therapies prior to screening who have not achieved the following treatment durations:
  - Erythropoietin or immunosuppressants for at least 8 weeks;
  - Systemic corticosteroids for at least 4 weeks;
  - Iron supplements, vitamin B12, or folic acid for at least 4 weeks;
  - Anticoagulants: Vitamin K antagonists for at least 4 weeks with stable international normalized ratio (INR) (as determined by the investigator), low molecular weight heparin for at least 4 weeks;
  - Hypoxic-inducing factor prolyl hydroxylase inhibitors (HIF-PHI) for at least 8 weeks;
  - Androgens for at least 4 weeks;
- A history of bone marrow/hematopoietic stem cell or solid organ transplantation;
- Alanine aminotransferase (ALT),  $\gamma$ -glutamyl transpeptidase (GGT), or alkaline phosphatase (ALP)  $> 3 \times \text{ULN}$  at screening; - Positive HIV antibody, active syphilis infection, positive HBsAg, active HCV infection, or active tuberculosis infection at screening;
- ... and 4 more (see full listing online)

## Locations (1 total)

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TianJin Medical University General Hospital, Tianjin, China

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<https://clinicaltrials.gov/study/NCT06978699>

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