

Evaluate The Efficacy, Safety, Pharmacokinetics And Pharmacodynamics Of EVER001

NCT05800873

Status	RECRUITING
Phase	Phase 1
Sponsor	Everest Medicines (China) Co.,Ltd.
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (4)

- Having clinical diagnosis of primary membranous nephropathy, as verified by biopsy.
- Have positive anti-PLA2R autoantibody test results ≥ 20 relative units (RU)/ml.
- During screening at least one testing of proteinuria must be ≥ 3.5 g/24h.
- Have nephrotic range proteinuria for at least 8 weeks prior to Day 1 and no improvement ($\geq 50\%$ reduction) despite supportive therapy of ACE inhibitor or ARB unless contraindicated, for patients who have two tests of proteinuria during screening ≥ 8.0 g/24h, the duration of nephrotic range proteinuria for at least 8 weeks is not required.

Exclusion (9)

- Non-primary membranous nephropathy or other condition affecting the kidney.
- eGFR at screening ≤ 45 mL/min/1.73m² or kidney function not stable .
- Uncontrolled hypertension .
- Serum albumin level at screening ≤ 25 g/l.
- Have received: B-cell targeted therapy except rituximab at any time;Rituximab and the biosimilars within 2 years (participants with rituximab treatment between 1 and 2 years prior to Day 1 are eligible if there is documented evidence of B-cell repopulation to $\geq 90\%$ of Lower Limits of Normal Range.); Cyclophosphamide or Chlorambucil within 180 days;other immunosuppressive/immunomodulatory agents within 90 days;greater than 30mg/day prednisone or equivalence within 30 days.

... and 4 more (see full listing online)

Locations (19 total)

The Second Xiangya Hospital Of Central South University, Changsha, Changsha, China
The First Affiliated Hospital of PLA Army Medical University, Chongqing, Chongqing Municipality, China
The Third Affiliated Hospital, Sun Yat Sen University, Guangzhou, Guangdong, China
... and 16 more locations

<https://clinicaltrials.gov/study/NCT05800873>

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