Iptacopan in Patients With ANCA Associated Vasculitis

Last Update: Jul 20, 2025
A Randomized, Controlled Study to Evaluate LNP023 (Iptacopan) in Patients With Active ANCA-associated Vasculitis
ClinicalTrials.gov Identifier:
NCT06388941
Novartis Reference Number:CLNP023R12201
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The purpose of this study is to evaluate the efficacy and safety of iptacopan compared to standard of care (SOC) to induce and maintain remission in study participants with active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA), when used in combination with rituximab (RTX) induction. The trial will also assess the impact of iptacopan on disease relapses, evolution of renal function and proteinuria, GC side effects, patients' immune status, and QoL. This is a randomized, controlled study to evaluate the efficacy and safety of iptacopan in combination with RTX induction therapy for the treatment of newly diagnosed or relapsed patients with active GPA or MPA.

Condition
Anti-Neutrophil Cytoplasm Antibodies (ANCA) Associated Vasculitis
Phase
Phase2
Overall Status
Recruiting
Number of Participants
78
Start Date
Aug 05, 2024
Completion Date
Oct 05, 2027
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

Iptacopan

LNP023 administered orally
Drug

Placebo

Matching placebo administered orally
Drug

Rituximab

Standard of care

Eligibility Criteria

Inclusion Criteria:

* Newly diagnosed or relapsed GPA and MPA (according to the 2022 ACR/EULAR classification criteria for GPA and MPA) requiring treatment with RTX and GC as per investigator's judgement.
* BVAS assessment with ≥1 major item, or ≥3 minor items, or ≥2 renal items at Screening.
* Positive antibody test for anti-proteinase 3 (PR3) or anti-myeloperoxidase (MPO) antibodies at Screening or with history of documented evidence of a positive antibody test.

Exclusion Criteria:

* Other systemic disease which constitutes the primary illness, including but not limited to: eosinophilic granulomatosis with polyangiitis (EGPA), moderate to severe systemic lupus erythematosus, IgA vasculitis (Purpura Schönlein-Henoch), rheumatoid vasculitis, Sjögren's syndrome, anti-glomerular basement membrane (GBM) disease, cryoglobulinemic vasculitis, autoimmune hemolytic anemia, autoimmune lymphoproliferative syndrome or mixed connective tissue disease.
* Alveolar hemorrhage requiring invasive pulmonary ventilation support at Screening.
* Severe kidney disease defined as estimated glomerular filtration rate (eGFR) \<15 mL/minute/1.73m2, or kidney failure defined as receiving renal replacement therapy such as hemo(dia)filtration, hemo-/peritoneal dialysis, or having received a kidney transplant.
* Received plasma exchange/-pheresis within 12 weeks prior to Screening.

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Recruiting

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