Safety and Efficacy of Tarperprumig in Adult Participants With Anti-Neutrophil Cytoplasmic Antibody (ANCA)-Associated Vasculitis

NCT07160608

Status	RECRUITING
Phase	Phase 2
Sponsor	Alexion Pharmaceuticals, Inc.
Enrollment	75 participants

Key Eligibility Criteria

Inclusion (3)

- Newly diagnosed or relapsing ANCA-associated vasculitis, GPA and MPA subtypes consistent with the 2022 ACR/EULAR classification criteria for GPA and MPA for whom treatment with rituximab or cyclophosphamide is considered.
- Positive test for antibodies to either PR3-ANCA or MPO-ANCA at Screening or in the past by a quantitative assay (for example, ELISA, bead assay).
- At least one major item, or at least 3 minor items, or at least 2 renal items in the BVAS.

Exclusion (4)

- Other systemic diseases that, in the judgment of the Investigator, constitute the primary illness, including but not limited to: eosinophilic granulomatosis with polyangiitis (EGPA), systemic lupus erythematosus, IgA nephropathy and/or IgA associated vasculitis with or without Henoch-Schonlein purpura, rheumatoid vasculitis, Sjogren's syndrome, anti-GBM disease, cryoglobulinemic vasculitis, autoimmune hemolytic anemia, or mixed connective tissue disease.
- Alveolar hemorrhage requiring invasive pulmonary ventilation support at Screening.
- Any diseases or conditions that, in the judgment of the Investigator, present a substantial clinical risk to participate in this study.
- For patients with a previous diagnosis of CKD, patients known to have a stable eGFR for greater than 3 months prior to Screening and a decline less than 25% of previous eGFR at Screening will be excluded.

Locations (78 total)

Research Site, Ciudad de Buenos Aires, Argentina
Research Site, Ciudad de Buenos Aires, Argentina
Research Site, La Plata, Argentina
... and 75 more locations