Efficacy and Safety Study of Ravulizumab IV in Pediatric Participants With NMOSD

NCT05346354

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Alexion Pharmaceuticals, Inc.
Enrollment	12 participants

Key Eligibility Criteria

Inclusion (7)

- Participants must be anti-AQP4 Ab-positive and have a diagnosis of NMOSD as defined by the 2015 international consensus diagnostic criteria.
- Complement inhibitor treatment-naïve participants must have had at least 1 attack or relapse in the last 12 months prior to the Screening Period.
- Expanded Disability Status Scale (EDSS) score d 7.
- Eculizumab-experienced participants must be clinically stable per Investigator for 30 days and have been treated with eculizumab in Study ECU-NMO-303 for at least 90 days prior to screening with no missed doses within 2 months prior to Day 1.
- Participants who enter the study receiving supportive IST(s) (eg, corticosteroid, azathioprine \[AZA\], mycophenolate mofetil \[MMF\], methotrexate \[MTX\], tacrolimus \[TAC\], cyclosporin \[CsA\], or cyclophosphamide \[CYC\]) for the prevention of relapse, either in combination or monotherapy, must be on a stable dosing regimen of adequate duration prior to Screening and remain on a stable dosing regimen during the Screening Period.

... and 2 more (see full listing online)

Exclusion (5)

- Use of rituximab within 3 months prior to screening.
- Currently treated with a biologic medications (other than eculizumab) that may affect immune system functioning, or has stopped treatment with a biologic medication that may affect immune system functioning, and 5 half lives of the medication have not elapsed by the time of the Screening Visit.
- Use of intravenous immunoglobulin (IVIg) or plasma exchange (PE) within 3 weeks prior to Screening.
- Participation in another investigational drug or investigational device study (other than Study ECU-NMO-303) within 5 half lives of that investigational product (if known) or 30 days before initiation of the first dose of study drug, whichever is longer.
- Use of immunomodulatory therapies for multiple sclerosis within 3 months prior to Screening.

Locations (21 total)

Research Site, Washington D.C., District of Columbia, United States
Research Site, Miami, Florida, United States
Research Site, Boston, Massachusetts, United States
... and 18 more locations