A Study to Evaluate the Safety and Efficacy of Satralizumab in Participants With Neuromyelitis Optica Spectrum Disorder (NMOSD)

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

• Participants aged less than 18 years at the time of informed consent for Study BN40898 can continue treatment with a combination of oral corticosteroids and either AZA or MMF

• Participated in Study BN40898 or Study BN40900 with satralizumab in NMOSD, are on ongoing satralizumab treatment and were anti-aquaporin-4 IgG antibody (AQP4-IgG) seropositive at screening in these studies. Participants with NMOSD who were AQP4-IgG seronegative at screening in Study BN40898 or Study BN40900 can be enrolled if the investigator considers the continued treatment with satralizumab to be beneficial for the participant

• For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use adequate contraception during the treatment period and for 3 months after the final dose of satralizumab.

Exclusion Criteria:

• Pregnant or breastfeeding, or intending to become pregnant during the study or within 3 months after the final dose of study drug. Women of childbearing potential must have a negative urine pregnancy test result on the baseline visit prior to initiation of study drug

• Evidence of any serious uncontrolled concomitant diseases that may preclude participation including nervous system disease, cardiovascular disease, hematologic/hematopoiesis disease, respiratory disease, muscular disease, endocrine disease, renal/urologic disease, digestive system disease, congenital or acquired severe immunodeficiency

• Known active infection that requires delaying the next satralizumab dose at the time of enrollment

• NMOSD relapse at the time of enrollment

• Laboratory abnormalities at the last assessment in Study BN40898 or Study BN40900 that preclude re-treatment with satralizumab

Conditions & Interventions

Interventions:
Drug: satralizumab, Drug: azathioprine (AZA), Drug: mycophenolate mofetil (MMF), Drug: oral corticosteroids
Conditions:
Neuromyelitis Optica Spectrum Disorder

More Information

Contact(s): Reference Study ID Number: WN42349 www.roche.com/about_roche/roche_worldwide.htm - global-roche-genentech-trials@gene.com
Principal Investigator:
Phase: Phase 3
IRB
Number:
System ID: NCT04660539

Thank you for choosing StudyFinder. Please visit http://studyfinder.cctr.vcu.edu to find a Study which is right for you and contact ctrrecruit@vcu.edu if you have questions or need assistance.