ForPatients
by Roche

Neuromyelitis OpticaNeuromyelitis optica spectrum disorder (NMOSD)

Efficacy and Safety Study of Satralizumab (SA237) as Add-on Therapy to Treat Participants With Neuromyelitis Optica (NMO) and NMO Spectrum Disorder (NMOSD)

Trial Status	Trial Runs In	Trial Identifier
Completed	11 Countries	NCT02028884 2013-003752-21 SA-307JG BN40898

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Multicenter, Randomized, Addition to Baseline Treatment, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Satralizumab (SA237) in Patients With Neuromyelitis Optica (NMO) and NMO Spectrum Disorder (NMOSD)

Trial Summary:

The objective of this study is to evaluate the efficacy, safety, pharmacodynamic, pharmacokinetic, and immunogenic profiles of satralizumab, compared with placebo, in addition to baseline immunosuppressive treatment in participants with NMO and NMOSD.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT02028884 2013-003752-21 SA-307JG BN40898
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#12 Years & # 74 Years	No

Inclusion Criteria:

- Patients must be diagnosed as having either neuromyelitis optica (NMO) or NMO spectrum disorder (NMOSD), defined as the following:

    - NMO as defined by Wingerchuk et al. 2006 criteria (requires all of the following 3 criteria: I. Optic neuritis, II. Acute myelitis, III. At least two of three supportive criteria: Contiguous spinal cord lesion identified on a magnetic resonance imaging (MRI) scan extending over 3 vertebral segments; Brain MRI not meeting diagnostic criteria for multiple sclerosis (MS); NMO-IgG seropositive status)
    - NMOSD as defined by either of the following Wingerchuk 2007 criteria with anti-AQP4 antibody (Ab) seropositive status at screening (i. Idiopathic single or recurrent events of longitudinally extensive myelitis [#3 vertebral segment spinal cord MRI lesion]; ii. Optic neuritis: recurrent or simultaneous bilateral); For patients aged 12 to 17 years, a minimum of 4 patients should be positive for anti-AQP4Ab status at screening
- Clinical evidence of at least 2 documented relapses (including first attack) in the last 2 years prior to screening, at least one of which has occurred in the 12 months prior to screening
- EDSS score from 0 to 6.5 inclusive at screening
- Age 12 to 74 years, inclusive at the time of informed consent
- One of the following baseline treatments must be at stable dose as a monotherapy for 8 weeks prior to baseline: Azathioprine; Mycophenolate mofetil; Oral corticosteroids. For participants aged 12 to 17 years, either of the following baseline treatments for relapse prevention can be allowed: Azathioprine + oral corticosteroids; Mycophenolate mofetil + oral corticosteroids
- Ability and willingness to provide written informed consent and to comply with the requirements of the protocol

For adolescents who may be enrolled after the end of the double-blind period, the inclusion criterion 2 is as follows (other criteria are same): Clinical evidence of at least 2 documented relapses (including first attack) prior to screening.

Exclusion Criteria:

Exclusion criteria related to previous or concomitant therapy:

- Any previous treatment with IL-6 inhibitory therapy (e.g. tocilizumab), alemtuzumab, total body irradiation or bone marrow transplantation at any time
- Any previous treatment with anti-CD20, eculizumab, belimumab, interferon, natalizumab, glatiramer acetate, fingolimod, teriflunomide or dimethyl fumarate within 6 months prior to baseline
- Any previous treatment with anti-CD4, cladribine or mitoxantrone within 2 years prior to baseline
- Treatment with any investigational agent within 3 months prior to baseline

Exclusions for general safety:

- Pregnancy or lactation
- For patients of reproductive potential, a positive result from a serum pregnancy test at screening, or not willing to use reliable means of contraception (physical barrier [patient or partner] in conjunction with a spermicidal product, contraceptive pill, patch, injectables, intrauterine device or intrauterine system) during the treatment period and for at least 3 months after the last dose of study drug
- Any surgical procedure (except for minor surgeries) within 4 weeks prior to baseline
- Evidence of other demyelinating disease or progressive multifocal leukoencephalopathy (PML)
- Evidence of serious uncontrolled concomitant diseases that may preclude patient participation, such as: other 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 (excluding fungal infections of nail beds or caries dentium) within 4 weeks prior to baseline

- Evidence of chronic active hepatitis B or C
- History of drug or alcohol abuse within 1 year prior to baseline
- History of diverticulitis that, in the Investigator's opinion, may lead to increased risk of complications such as lower gastrointestinal perforation
- Evidence of active tuberculosis (TB; excluding patients receiving chemoprophylaxis for latent TB infection)
- Evidence of active interstitial lung disease
- Receipt of any live or live attenuated vaccine within 6 weeks prior to baseline
- History of malignancy within the last 5 years, including solid tumors, hematologic malignancies and in situ carcinoma (except basal cell and squamous cell carcinomas of the skin, or in situ carcinoma of the cervix uteri that have been completely excised and cured)
- History of severe allergic reaction to a biologic agent (e.g. shock, anaphylactic reactions)
- Active suicidal ideation within 6 months prior to screening, or history of suicide attempt within 3 years prior to screening
- Following laboratory abnormalities at screening*.
    - White blood cells (WBC) <3.0 x10^3/microliter (µL)
    - Absolute neutrophil count (ANC) <2.0 x10^3/µL
    - Absolute lymphocyte count <0.5 x10^3/µL
    - Platelet count <10 x 10^4/µL
    - Aspartate aminotransferase (AST) or alanine aminotranferase (ALT) >1.5 times the upper limit of normal (ULN) * If retest is conducted, the last value of retest before randomization must meet study criteria.

For adolescents who may be enrolled after the end of the double-blind period, the annotation in the exclusion criterion 20 is as follows (other criteria are same): * If retest is conducted, the last value of retest before baseline must meet study criteria