ForPatients
by Roche

Neuromyelitis OpticaNeuromyelitis optica spectrum disorder (NMOSD)

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

Trial Status	Trial Runs In	Trial Identifier
Completed	15 Countries	NCT02073279 SA-309JG 2015-005431-41 BN40900

The clinical trial information herein is sourced from public registries such as ClinicalTrials.gov, EuClinicalTrials.eu, and ISRCTN.com. Additional patient-friendly (lay) content has been prepared by Roche to support understanding.

Official Title:

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

Trial Summary:

The objectives of this study are to evaluate the efficacy, safety, pharmacodynamic, pharmacokinetic and immunogenic profiles of satralizumab in participants with NMO and NMOSD.

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT02073279 SA-309JG 2015-005431-41 BN40900
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 74 Years	No

Inclusion Criteria:

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

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- 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) 2. NMOSD as defined by either of following criteria with anti-aquaporin-4 (AQP4) antibody seropositive status at screening: i. Idiopathic single or recurrent events of longitudinally extensive myelitis (#3 vertebral segment spinal cord MRI lesion); ii. Optic neuritis, single, recurrent or simultaneous bilateral
- Clinical evidence of at least 1 documented relapse (including first attack) in last 12 months prior to screening
- Expanded Disability Status Scale (EDSS) score from 0 to 6.5 inclusive at screening
- Age 18 to 74 years, inclusive at the time of informed consent
- Ability and willingness to provide written informed consent and to comply with the requirements of the protocol

Exclusion Criteria:

- Clinical relapse onset (including first attack) within 30 days prior to baseline

Exclusion Criteria Related to Previous or Concomitant Therapy:

- Any previous treatment with interleukin 6 (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, anti-BLyS monoclonal antibody (e.g., belimumab), any other treatment for prevention of multiple sclerosis (MS) relapse (e.g., interferon, natalizumab, glatiramer acetate, fingolimod, teriflunomide or dimethyl fumarate) within 6 months prior to baseline
- Any previous treatment with anti-CD4, cladribine, cyclophosphamide 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 participants of reproductive potential, a positive result from a serum pregnancy test at screening, or not willing to use reliable means of contraception (physical barrier [participants 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 participant participation, as described; 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 (excluding participants receiving chemoprophylaxis for latent tuberculosis infection)
- Evidence of active interstitial lung disease

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- 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
- History of Stevens-Johnson syndrome
- Following laboratory abnormalities at screening*.
- White blood cells <3.0 x10^3/microliter (µL) 2. Absolute neutrophil count <2.0 x 10^3 /µL 3. Absolute lymphocyte count <0.5 x 10^3 /µL 4. Platelet count <10 x 10^4 /µL 5. Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) >1.5 times the upper limit of normal.
- If retest is conducted, the last value of retest before randomization must meet study criteria.

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