ForPatients
by Roche

Neuromyelitis optica spectrum disorder (NMOSD)

A clinical trial to look at the long-term safety and effects of satralizumab in people with neuromyelitis optica spectrum disorder.

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

Trial Status	Trial Runs In	Trial Identifier
Completed	18 Countries	NCT04660539 2020-003413-35 WN42349

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, Single Arm, Open-Label Study to Evaluate the Long-Term Safety and Efficacy of Satralizumab in Patients With Neuromyelitis Optica Spectrum Disorder (NMOSD)

Trial Summary:

This multicenter, single-arm, open-label study will evaluate the long-term safety and efficacy of satralizumab in participants with neuromyelitis optica spectrum disorder (NMOSD) who completed open-label extension (OLE) period of studies BN40898 and BN40900. Participants will receive satralizumab as monotherapy or in combination with one of the following background immunosuppressive treatments: azathioprine (AZA), mycophenolate mofetil (MMF), or oral corticosteroids.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT04660539 2020-003413-35 WN42349
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

How does the SAkuraMoon clinical trial work?
This clinical trial is recruiting people who have a type of disease called neuromyelitis optica spectrum disorder or NMOSD. In order to take part, patients must be receiving ongoing

treatment with satralizumab as part of either the BN40898 (also called ‘SAkuraSky’) or BN40900 (also called ‘SAkuraStar’) clinical trials. Patients who have competed either of these studies will be eligible for this clinical trial. The purpose of this clinical trial is to look at the long-term safety and effects of satralizumab in patients who have participated in either of these two clinical trials and are willing to continue with satralizumab treatment.

How do I take part in this clinical trial?
To be able to take part in this clinical trial, you must have been diagnosed with neuromyelitis optica spectrum disorder and participated in either the BN40898 (‘SAkuraSky’) or BN40900 (‘SAkuraStar’) studies. If you are pregnant or breast feeding, you will not be able to take part.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. They will give you all the information you need to make your decision about taking part in the clinical trial.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, women who can become pregnant will need to either not have heterosexual intercourse or use contraceptives for safety reasons.

What treatment will I be given if I join this clinical trial?
Everyone who joins this clinical trial will continue to be given satralizumab as an injection under the skin into the abdomen or thigh every 4 weeks. You may also continue to be given other treatments known as ‘immunosuppressants’, such as azathioprine (or AZA), mycophenolate mofetil (or MMF), or oral corticosteroids.

How often will I be seen in follow-up appointments and for how long?
You will be given satralizumab for up to 3 years. You will receive treatment every 4 weeks. Treatment may be given in the clinic, or self-administered at home with a prefilled syringe.

You are free to stop this treatment at any time.

You will still be seen regularly by the clinical trial doctor at least every 12 to 24 weeks. These hospital visits will include the same checks to see how you are responding to the treatment and physical examinations and laboratory tests that you are used to from your current study. Any side effects that you may be having will be assessed throughout treatment with satralizumab and for a further 3 months after treatment is completed.

What happens if I am unable to take part in this clinical trial?

If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on the specific For Patient page or follow this link to ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT04660539

Trial-identifier: NCT04660539

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