

EFFICACY & SAFETY STUDY OF SA237 AS MONOTHERAPY TO TREAT NMO AND NMOSD

SPONSORED BY CHUGAI PHARMACEUTICALS

STUDY DETAILS

This research is being conducted to evaluate the efficacy, safety, pharmacodynamic, pharmacokinetic and immunogenic profiles of a humanized anti-human IL-6R neutralizing monoclonal antibody (SA237) in patients with Neuromyelitis Optica (NMO) and Neuromyelitis Optica Spectrum Disorder (NMOSD). This study is being conducted in the US and Canada and will enroll seventy (70) patients to participate in this research.

Mechanism of Action: SA237 is a humanized anti-human IL-6R neutralizing monoclonal antibody that was designed by applying recycling antibody technology to the approved anti-IL6 receptor antibody, tocilizumab, which is currently marketed as a treatment for rheumatoid arthritis (RA), systemic juvenile idiopathic arthritis, polyarticular juvenile idiopathic arthritis and Castleman's disease. The recycling antibody technology enabled SA237 to bind to IL-6 receptor multiple times and be slowly cleared from plasma, which is expected to contribute to improvement and is convenient with once monthly dosing frequency. The longer plasma half-life of SA237 compared with tocilizumab was confirmed based on the results of a non-clinical study and a Phase 1 study in healthy volunteers.

CONTACT INFORMATION

If you are interested in participating, please contact:

Clinical trials information clinical-trials@chugai-pharm.co.jp

SA237 Clinical trial sa237@chugai-pharm.co.jp

<http://clinicaltrials.gov/ct2/show/study/NCT02073279?term=SA237&rank=1>

For more information on the European/Asian trial, please visit:

<https://www.clinicaltrialsregister.eu/ctr-search/search?query=SA237>

ELIGIBLE PARTICIPANTS

Inclusion Criteria:

1. NMO or NMOSD
2. Age 18 to 74 years, inclusive at the time of informed consent.

Exclusion Criteria:

1. Pregnancy or lactation.
2. Evidence of other demyelinating disease or PML.
3. Known active infection (excluding fungal infections of nail beds or caries dentium) within 4 weeks prior to baseline.

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Have you read the **TMA BLOG** (<https://myelitis.org/category/resources/tma-blog>) lately? We publish weekly stories and articles written by individuals living with rare neuro-immune diseases, caregivers and families, as well as leading researchers and clinicians. The blog covers a wide variety of relevant topics, including stories about your experiences living with a rare neuro-immune disease, clinical care and management updates, new research studies, TMA awareness and education program announcements.

You don't have to wait for the latest publication of the TMA Newsletter or try to remember to visit the TMA website in order to receive the most up-to-date information on the latest research and findings in the field of rare neuro-immune disorders. It's easy to stay informed about the latest events, programs and activities of The Transverse Myelitis Association. You can have all of this information delivered directly to your inbox so you won't miss a thing! To receive a weekly email with our latest blog posts in your inbox, please go to <http://eepurl.com/xuoGr>.