ForPatients
by Roche

Guillain-Barré Syndrome

A Study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of Crovalimab in Participants With Guillain-Barré Syndrome (GBS)

Trial Status	Trial Runs In	Trial Identifier
Withdrawn		NCT05494619 2021-002968-49 BN43118

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 Phase III Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy, Safety, Pharmacokinetics and Pharmacodynamics of Crovalimab in Patients With Guillain-Barré Syndrome

Trial Summary:

The purpose of this study is to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of crovalimab compared with placebo as an add-on therapy to intravenous immunoglobulin (IVIg) in participants with severe GBS.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT05494619 2021-002968-49 BN43118
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Body weight >= 40 kg at screening
- Confirmed diagnosis of GBS according to National Institute of Neurological Disorders and Stroke (NINDS) classification system
- Onset of weakness due to GBS within 2 weeks before randomization
- Able to start the first dose of blinded study drug within 2 weeks of onset of weakness

- Able to climb a flight of stairs prior to GBS
- Unable to walk independently for >=10 meters (FG >=3) with deteriorating weakness as per investigator judgment, or FG 4 or FG 5 on the GBS-DS. These criteria must be satisfied during screening.
- Undergoing or starting IVIg treatment (400 mg/kg QD for 5 days) prior to first blinded study drug administration. Participants must be able to receive the first dose of blinded study drug before the final dose of IVIg during the 5-day period of IVIg treatment.
- A record of vaccination (<=3 years) against Neisseria meningitidis, Haemophilus influenzae type B, and Streptococcus pneumonia prior to initiation of blinded study drug, in accordance with most current local guidelines as applicable for patients with complement deficiency.
- Adequate hepatic and renal function
- For female participants of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception during the treatment period and for up to 11 months after the final dose of study treatment.

Exclusion Criteria:

- Clear clinical and historical evidence of significant or disabling acute or chronic peripheral neuropathy of alternative etiology, chronic inflammatory demyelinating polyneuropathy, severe vitamin deficiency, porphyria, or diagnosis of Charcot Marie Tooth disease or other genetic neuropathy
- History of requiring a permanent aid to walk prior to GBS
- Treatment with plasmapheresis or PLEX after GBS diagnosis, or a plan to receive this treatment
- Receipt of systemic immunosuppressive treatment within 4 weeks prior to randomization
- Known or suspected hereditary complement deficiency
- Known or suspected immune deficiency
- Recent use (up to five half-lives) of treatment with complement inhibitors (e.g., 10 weeks for eculizumab, 41 weeks for ravulizumab)
- History of Neisseria meningitidis infection within 12 months prior to screening and up to first blinded study drug administration (Day 1)
- Contraindication that would prevent use of any class of antibiotics as Neisseria meningitides prophylaxis
- Immunization with a live attenuated vaccine within 1 month before first blinded study drug administration (Day 1)
- Participants who have been partially or fully vaccinated against SARS-CoV-2 with a locally approved vaccine are eligible to be enrolled in the study, 3 days or longer after inoculation.
- Recent SARS-CoV-2 infection (defined by a positive PCR test within the 2-week period prior to screening), or ongoing symptoms of active COVID-19
- Any systemic bacterial, viral, or fungal infection ongoing at screening and up to the first blinded study drug administration (Day 1) which, in the investigators' judgment, is active and could potentially be worsened by immunosuppression
- Current hepatitis B, hepatitis C, or HIV infection
- History of malignancy within 5 years prior to screening and up to the first blinded study drug administration (Day 1)
- History of hypersensitivity, allergic, or anaphylactic reactions to crovalimab or IVIg, including hypersensitivity to human, humanized, or murine monoclonal antibodies, or known hypersensitivity to any constituent of the products
- For participants with prior exposure to anti-CD20 agents, most recent anti-CD20 treatment within 6 months prior to screening
- Substance abuse within 12 months prior to screening, in the investigator's judgment
- Active suicidal ideation within 6 months prior to screening or history of suicide attempt within 3 years prior to screening

- Concurrent disease, treatment, procedure or surgery, or abnormality in clinical laboratory tests that could interfere with the conduct of the study, may pose any additional risk for the patient, or would, in the opinion of the investigator, preclude the patient's safe participation in and completion of the study
- Participation in another interventional treatment study with an investigational agent or use of any experimental therapy within 28 days of screening or within five half-lives of that investigational product, whichever is longer
- Splenectomy <= 6 months prior to screening
- Selective IgA deficiency with development of antibodies to IgA
- Only applicable for participants receiving proline-containing IVIg products: History or ongoing hyperprolinaemia type I or II at screening
- Only applicable for participants receiving sucrose/glucose/maltose-containing IVIg products: History of or ongoing diabetes mellitus or use of concomitant nephrotoxic medications
- Pregnancy or breastfeeding, or intention of becoming pregnant during the study or within 11 months after the final dose of crovalimab.