A Study to Investigate the Efficacy, Safety and Tolerability of Remibrutinib Versus Placebo in Adult Patients With Generalized Myasthenia Gravis

Last Update: Apr 24, 2025
A Randomized, Double-blind, Placebo-controlled Phase III Study to Evaluate the Efficacy, Safety, and Tolerability of Remibrutinib in Patients With Generalized Myasthenia Gravis, Followed by an Open-label Extension Phase
ClinicalTrials.gov Identifier:
NCT06744920
Novartis Reference Number:CLOU064O12301
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

A study to evaluate the efficacy, safety and tolerability of Remibrutinib versus placebo in adult patients with Generalized Myasthenia Gravis who are on stable, standard-of-care (SOC) treatment. This study is a randomized, double-blind, placebo-controlled, multicenter, Phase III study, to evaluate the efficacy, safety and tolerability of remibrutinib in gMG patients who are on stable SOC treatment. Approximately 180 eligible participants will be randomized in a ratio of 1:1, to receive either remibrutinib or matching placebo.

The study consists of a Core Part (6-months double-blind treatment) and an Extension Part (up to 60-month open-label treatment).

Condition
Generalized Myasthenia Gravis
Phase
Phase3
Overall Status
Recruiting
Number of Participants
180
Start Date
Feb 07, 2025
Completion Date
Feb 26, 2033
Gender
All
Age(s)
18 Years - 75 Years (Adult, Older Adult)

Interventions

Other

Placebo

Placebo
Drug

Remibrutinib (Blinded)

Remibrutinib (Blinded) active treatment
Drug

Remibrutinib (Open Label)

Remibrutinib (Open Label) active treatment

Eligibility Criteria

Inclusion Criteria:

* Adult patients with gMG (age 18-75 years)
* Confirmed diagnosis of Myasthenia Gravis Foundation of America (MGFA) Class II-IV gMG at screening and likely not in need of a respirator for the duration of the study, as judged by the Investigator
* Documented evidence of positive serologic testing for AChR+ antibody or MuSK+ antibody at screening, OR seronegative for both AChR and MuSK antibodies at screening
* Baseline MG-ADL score ≥ 6 with ≥ 50% of the total score due to non ocular symptoms
* Participants who have been on a stable dose of standard-of-care treatment as specified in the protocol
* Able to safely swallow the study medication according to investigator clinical judgement based on a bedside swallowing test or another formal swallowing test in line with local practice, both at Screening and Baseline

Exclusion Criteria:

* Prior to baseline have been treated with intravenous immunoglobulins or plasma exchange (IVIg/PLEX) in the past month, with rituximab in the past 6 months, eculizumab in the past 2 months, ravulizumab or other complement inhibitors in the past 3 months, efgartigimod or other anti-FcRn therapies in the past 3 months, or had a thymectomy in the past 6 months or a planned thymectomy during the trial period
* Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using highly effective methods of contraception during dosing and for 1 week after stopping of study treatment

Other protocol-defined inclusion/exclusion criteria may apply.

United States

Dent Neurological Institute

Recruiting

Buffalo,New York,14209,United States

Allison Clarke

Email: aemborsky@dentinstitute.com

Bennett Myers

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

Novartis Pharmaceuticals

Phone: +41613241111
Email:

Novartis Pharmaceuticals

Phone: 1-888-669-6682
Email: novartis.email@novartis.com

Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06744920*

List of links present in page

1. https://clinicaltrials.gov/ct2/show/NCT06744920
2. #trial-eligibility
3. mailto:aemborsky@dentinstitute.com
4. tel:+41613241111
5. mailto:
6. tel:1-888-669-6682
7. mailto:novartis.email@novartis.com