A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study with an Open-label Extension Period to Evaluate the Efficacy and Safety of Telitacicept in Patients with Generalized Myasthenia Gravis (RemeMG)

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Objectives:

Here we present the study design of our global pivotal phase 3, double-blind, placebo-controlled study with an open-label extension (OLE) in adult patients with gMG.

Background:

Myasthenia gravis (MG) is an autoimmune disease that affects the neuromuscular junction on the postsynaptic membrane. The predominant manifestation is fatigable weakness, affecting limb, respiratory, bulbar, and ocular muscles. Current therapies treat the symptoms of MG symptomatically, induce nonspecific immunosuppression, remove pathogenic antibodies, or block postsynaptic membrane damage caused by complement activation.

Telitacicept is a novel TACI-Fc fusion protein that targets B-cell activating factor (BAFF) and a proliferating-inducing ligand (APRIL), modulate B-cell survival and pathogenic antibody reduction both upstream and downstream. This suppression at the proximal portion of the immune response may alleviate symptoms of autoimmune diseases such as gMG.

Data from phase 2 (NCT04302103), and phase 3 (NCT05737160) studies of telitacicept showed efficacy and safety in adults with acetylcholine receptor (AChR) autoantibody positive gMG.

Methods:

The study will enroll ~180 adult patients, with AChR or muscle specific tyrosine kinase (MuSK) autoantibody positive gMG and inadequate response to stable standard-of-care therapies. Key eligibility criteria include confirmed diagnosis of gMG, Myasthenia Gravis Foundation of America (MGFA) Class II-IV, Myasthenia Gravis-Activities of Daily Living (MG-ADL) score ≥ 6 with less than 50% of the total score due to ocular symptoms and Quantitative MG (QMG) score ≥ 8 with 4 items score at least 2 at screening and baseline.

The study will consist of a screening period of ≤4 weeks, a 24-week double-blind placebo-controlled phase, 1:1 randomization to either placebo or telitacicept subcutaneous weekly, and an open label extension (OLE) of 48 weeks. The primary outcome is the mean change from baseline in MG-ADL score at Week 24.

Results:

Study enrollment is currently ongoing.

Conclusions:

The study will assess the efficacy, safety, and PK/PD of telitacicept in adult patients with gMG.