Global Phase 3 Study to Evaluate the Efficacy and Safety of Telitacicept in Patients with Generalized Myasthenia Gravis (RemeMG)

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Objectives:

To 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 generalized myasthenia gravis (gMG).

Background:

Myasthenia gravis is an autoimmune disease that affects the postsynaptic membrane of the neuromuscular junction. The predominant manifestation is fatigable weakness, affecting limb, respiratory, bulbar, and ocular muscles. Current therapies treat the symptoms of gMG, 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) and modulates B-cell survival, resulting in pathogenic antibody reduction. 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 a confirmed diagnosis of gMG, Myasthenia Gravis Foundation of America (MGFA) Class II-IV, Myasthenia Gravis-Activities of Daily Living (MG-ADL) score ≥6 with <50% of the total score due to ocular symptoms, and Quantitative MG (QMG) score ≥8, with 4 items having a score ≥2 at screening and baseline. Other eligibility criteria include

positive AChR or muscle-specific tyrosine kinase (MuSK) autoantibodies or inadequate response to standard-of-care therapies.

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 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.

Disclosures:

1. Mamatha Pasnoor is a University of Kansas site principal investigator for RemeGen MG trial; served as medical advisor or consultant for Alexion, Amgen, Annexon, argenx, BVBA, Catalyst, CSL Behring, Grifols, Immunovant Pharmaceuticals, Jansen, Johnson and Johnson, Momenta, Takeda, and Terumo BCT; serves on the board of directors for the Myasthenia Gravis Association (MGA).
2. George Li is a consultant for RemeGen Biosciences and is the investigator for this phase 3 study.
3. Ali A. Habib has received research support/honoraria from Alexion/AstraZeneca, Amgen, Arcellx, argenx, Cabaletta Bio, Cartesian, COUR Pharmaceuticals, GC Biopharma, Grifols, Immunovant, Jansen/J&J, Kyverna, MGNet (grant number: U54NS115054), Merck, Nkarta, NMD Pharma, Novartis, Regeneron, and UCB; has served on a Data and Safety Monitoring Board for Genentech/Roche, Immunis Biomedical, and the National Institutes of Health/National Institute of Neurological Disorders and Stroke; and has served on a Trial Steering Committee for Dianthus, Jansen/J&J, and Kyverna.
4. Shaida Khan is the site principal investigator for RemeGen MG trial at UT Southwestern Medical Center. She also serves as a consultant for UCB.
5. Bhupendra Khatri is Medical Director at the Center for Neurological Disorders at Ascension St. Francis Hospital and has received speaker and consulting fees from Alexion, Biogen, Bristol Myers Squibb, EMD Serono, Genentech, Genzyme, Horizon, Novartis, Terumo BCT, TG Therapeutics, and UCB.
6. Amit Sachdev has served as MSU site principal investigator for MG clinical trials sponsored by Alexion/AstraZeneca Rare Disease, argenx, COUR, Dianthus Therapeutics, EMD Serono, Immunovant, Johnson & Johnson, Novartis, UCB, and VOR. He has served as a speaker for

Alexion/AstraZeneca Rare Disease, Amgen, and argenx and participated on advisory boards for Alexion/AstraZeneca Rare Disease, Amgen, and Johnson & Johnson.

7. Said Beydoun has received research support from Abcuro, AB Science, ALS Healey Center, Immunovant, Janssen, Novartis, Regeneron, RemeGen, and Sanofi; and consulting and/or speaker honoraria from Alexion, Alnylam, Amgen, argenx, AstraZeneca, Catalyst, CSL Behring, Janssen, Pfizer, Takeda, and UCB.
8. Lawrence Meinert is an employee of Vor Biopharma Inc. and owns company stock.
9. Qing C. Zuraw is an employee of Vor Biopharma Inc. and owns company stock.
10. Tuan Vu is USF site principal investigator for MG clinical trials sponsored by Alexion/AstraZeneca Rare Disease, Amgen, argenx, Cartesian Therapeutics, COUR, Dianthus Therapeutics, EMD Serono, ImmunAbs, Immunovant, Johnson & Johnson, NMD Pharma, Novartis, Regeneron, UCB, and Vor. He has served as a speaker for Alexion/AstraZeneca Rare Disease, Amgen, argenx, and CSL Behring and participated on advisory boards for Alexion/AstraZeneca Rare Disease, Amgen, argenx, Dianthus Therapeutics, Johnson & Johnson, ImmunAbs, NMD Pharma, Regeneron, and Vor.