

Telitacicept for Generalized Myasthenia Gravis: Depth of Response Across 48 Weeks in a Phase 3 Study Conducted in China

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Introduction:

Autoreactive B cells are believed to have a critical role in generalized myasthenia gravis (gMG). B-cell activating factor (BAFF) and a proliferation-inducing ligand (APRIL) are involved in B-cell development, differentiation, maturation, and survival. Telitacicept, a novel TACI-Fc fusion protein that binds BAFF and APRIL, demonstrated efficacy and safety in adults with gMG in a 24-week phase 3 study.

Objectives:

To assess the depth and durability of clinical response with telitacicept in a phase 3 study conducted in China.

Methods:

Participants with anti-acetylcholine receptor or muscle-specific kinase autoantibody-positive gMG were randomized to telitacicept or placebo for 24 weeks followed by a 24-week open-label extension (OLE) in which all participants received telitacicept. Improvement in the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale and achievement of minimal symptom expression (MSE) was assessed in a post hoc analysis.

Results:

At week 24, 85.2% of participants in the telitacicept group achieved an improvement in MG-ADL of ≥ 5 from baseline compared with 6.0% in the placebo group. At week 48, the proportion of participants achieving improvement in MG-ADL of ≥ 5 from baseline was 94.3% in the telitacicept $\rightarrow$ telitacicept group and 74.5% in the placebo $\rightarrow$ telitacicept group. Among participants receiving telitacicept, the proportion achieving MSE at any time over 24 weeks was 27.3% and 42.1% over 48 weeks. Telitacicept was generally well tolerated over 48 weeks.

Summary/Conclusion:

Clinically meaningful improvements were observed in telitacicept-treated gMG participants during the randomized controlled period which were sustained during the OLE period in this post hoc analysis evaluating depth of response.

Disclosures:

Mingming Zhao, Nothing to declare

Hui Deng, Nothing to declare

Bitao Bu, Nothing to declare

Xu Zhang, Nothing to declare

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Jeremy Sokolove is an employee of Vor Biopharma Inc. and owns company stock.

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