

Trial results of new drug for generalized myasthenia gravis

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Argenx, a Belgium pharmaceutical company, recently announced that

The Lancet Neurology has published pivotal trial results from the Phase 3 ADAPT trial of efgartigimod, an FcRn antagonist, for the treatment of adults living with generalized myasthenia gravis (gMG). Efgartigimod is currently under review with the U.S. Food and Drug Administration (FDA) for the treatment of gMG with a Prescription Drug User Fee Act (PDUFA) target action date of December 17, 2021, and if approved, would be the first-and-only approved FcRn antagonist.

"Myasthenia gravis can have a devastating impact on a person's life and independence, potentially affecting one's ability to swallow, speak, walk and even breathe. In addition, each patient experiences the course of MG differently, which can make [disease management](#) unpredictable," said James F. Howard Jr., MD, Distinguished of Neuromuscular Disease and professor of medicine, neurology and allied health at the UNC School of Medicine and principal investigator for the ADAPT trial. "In the ADAPT trial, we observed clinically meaningful improvements in the first two weeks of dosing in a majority of patients treated with efgartigimod. These results are important for the MG community and I am hopeful efgartigimod will provide a first-in-class targeted therapy that can be dosed in an individual way for people living with this chronic autoimmune disease."

The ADAPT trial met its primary endpoint demonstrating significantly more acetylcholine receptor-antibody positive (AChR-Ab+) gMG patients were responders on the Myasthenia Gravis Activities of Daily Living (MG-ADL) score following treatment with efgartigimod compared with placebo (67.7% vs. 29.7%; p

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