Interim data suggest long-term treatment improves generalized myasthenia gravis disease scores

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Argenx SE, a Belgian drug maker, recently announced interim results from ADAPT+, an ongoing Phase 3, open-label, three-year extension

study evaluating long-term safety, tolerability and efficacy of VYVGART (efgartigimod alfa-fcab) for the treatment of adults with generalized myasthenia gravis (gMG). The data was presented on April 5, 2022, in an oral presentation at the 74th Annual Meeting of the American Academy of Neurology (AAN) by James F. Howard, Jr., MD, professor of neurology, medicine and allied health and principal investigator for the ADAPT trial.

"gMG can have a devastating impact on a person and their ability to lead a fulfilling life. For healthcare providers treating gMG patients, the ADAPT+ results provide greater understanding of how long-term treatment with VYVGART could help their patients overcome some of the daily limitations they face living with this debilitating disease," Howard said. "Patients who participated in ADAPT+ continued to experience consistent efficacy and safety over a year of treatment, reinforcing the potential benefit this targeted therapy can offer to this community."

Highlights of ADAPT+ interim analysis

139 patients received at least one dose of VYVGART in ADAPT+. As of the interim analysis, the mean treatment duration was 363 days. Efficacy analyses were based on 106 patients who are anti-acetylcholine receptor (AChR) antibody positive.

Patients who continued on long-term treatment with VYVGART experienced consistent and clinically meaningful improvement on both the Myasthenia Gravis Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) scales. The safety profile of long-term treatment (up to 10 treatment cycles) with VYVGART continued to be favorable and consistent with ADAPT.

Phase 3 ADAPT+ Study Design

The Phase 3 ADAPT+ trial is a long-term, single-arm, open-label, multicenter trial evaluating the efficacy and safety of VYVGART in patients with gMG. Ninety-one percent (151/167) of ADAPT patients entered the ADAPT+ study. A total of 106 AChR-Ab+ and 33 AChR-Ab– had received at least one dose of open-label VYVGART (including 66 ADAPT placebo patients). The remaining patients were either still responding to treatment from their last cycle in ADAPT, or dropped out between rollover. There were at least four weeks between cycles in the ADAPT+ study, with a maximum of ten cycles. The mean study duration was 363 days, resulting in 138 patient-years of observation.

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