patients who had previously received zilucoplan and who switched from placebo.

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Corticosteroid dose tapering in patients with generalised myasthenia gravis on zilucoplan: Interim analysis of RAISE-XT

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Background: In the Phase 3 RAISE study (NCT04115293), zilucoplan significantly improved MG-specific outcomes in patients with acetylcholine receptor autoantibody-positive generalised MG. After the first 12 weeks of the open-label extension study, RAISE-XT (NCT04225871), corticosteroid dose could be changed per the investigator's discretion. We evaluate changes in corticosteroid dose during treatment with zilucoplan in RAISE-XT. Methods: In RAISE-XT, adults who completed the Phase 2 or RAISE studies (N=200) self-administered daily subcutaneous zilucoplan 0.3mg/kg, either continuing with zilucoplan or switching from placebo. Primary outcome was incidence of treatment-emergent adverse events (TEAEs). We assessed (*post-hoc*) the proportion of patients who discontinued/reduced or increased corticosteroid dose relative to double-blind baseline up to Week 60. Results: At Week 60, 30% (n=18/60) and 22% (n=12/54) of patients receiving corticosteroids in the zilucoplan and placebo-switch groups, respectively, reduced/discontinued corticosteroids (mean dose reductions: 14mg and 16mg; mean [SD] CFB in MG-ADL scores: -5.00 [3.96] and -5.67 [6.89]. 12% (n=7/60) and 7% (n=4/54) of patients in the zilucoplan and placebo-switch groups, respectively, increased corticosteroid dose (~12mg mean increase in both groups). TEAEs occurred in 188 (94.0%) patients (data cut-off: 08 September 2022). Conclusions: While receiving zilucoplan, discontinuation or dose reduction in concomitant corticosteroids was possible with maintained efficacy.

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Real-world reduction in oral corticosteroid utilization following efgartigimod initiation in patients with generalized myasthenia gravis

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Background: Reducing oral corticosteroids (OCS) use can alleviate the risk of many adverse events related to long-term OCS use. Here, we evaluate real-world utilization of OCS among patients with generalized myasthenia gravis (gMG) over the first 6 months following efgartigimod initiation. Methods: Patients with gMG using OCS who initiated efgartigimod treatment were identified retrospectively from an open US medical and pharmacy claims database (IQVIA Longitudinal Access and Adjudication Data [LAAD], April 2016-April 2023). Average daily dose (ADD) of OCS was analyzed during the 3-month period preceding efgartigimod initiation, and at 3 and 6 months post-efgartigimod initiation. Results: Of 231 patients assessed, 17 (7.4%), 109 (47.1%), and 105 (45.5%) had baseline OCS ADD of 0–5 mg, 5–20 mg, or >20 mg, respectively. At 3 and 6 months post-efgartigimod, 82 (35%) and 99 (43%) patients, respectively, reduced ADD by ≥5 mg. Proportion of patients with ADD of 0–5 mg increased >3-fold (7% baseline vs. 26% 6 months post-efgartigimod) and proportion of patients with ADD of >20 mg decreased by 35% (45% baseline vs. 29% 6 months post-efgartigimod) following efgartigimod initiation. Conclusions: Approximately 43% of patients were able to decrease steroid use or achieved steroid-free status within 6 months of efgartigimod treatment initiation.

P.057

Achievement of minimal symptom expression in acetylcholine receptor antibody-positive participants treated with efgartigimod in ADAPT/ADAPT+

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Background: A key efficacy indicator in generalized myasthenia gravis (gMG) treatment is improvement in MG-ADL score. Minimal symptom expression (MSE, MG-ADL total score of 0 or 1) is explored as a novel proposed treatment target in gMG in the phase 3 study of intravenous efgartigimod, ADAPT, and its open-label extension, ADAPT+. Methods: Post hoc analyses of acetylcholine receptor antibody positive participants in ADAPT (n=129) and ADAPT+ (n=111) were performed. Results: In ADAPT, 44.6% receiving efgartigimod achieved MSE vs 10.9% of participants given placebo. Despite less frequent assessment during ADAPT+, 40.5% of participants achieved MSE. Eighty-one percent of participants treated with efgartigimod who achieved MSE in ADAPT also achieved MSE during ADAPT+; 23% who had not achieved MSE in ADAPT did in ADAPT+. Achieving MSE was associated with substantial improvements in QMG, MGC, MG-QoL15r, and EQ-5D-5L mean scores of 11.4, 16.0, 12.4, and 0.3 points, respectively, from baseline to best score (across all visits). These drastic improvements resulted in quality of life (QoL) comparable to that of healthy populations. MSE achievement also resulted in sustained improvements in these disease-specific and QoL measures. Conclusions: Participants who achieved MSE showed substantial and consistent improvements across multiple disease measures and experienced QoL comparable to that of healthy populations.