Effects of galcanezumab on acute medication use and health care resource utilization in treatment-resistant migraine: results from randomized, double blind, placebo-controlled clinical trial, conquer

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Introduction
Acute headache medication use (AHM) and health care resource utilization (HCRU) in patients with protocol-defined treatment-resistant migraine treated with galcanezumab (GMB).

Material and methods
In the 3-month double-blind (DB) study phase, patients with episodic or chronic migraine and 2-4 migraine preventive category failures due to lack of effectiveness or safety/tolerability, received GMB 120 mg/month (following initial 240 mg loading dose) or placebo (PBO); an optional 3-month open-label (OL) GMB treatment followed. AHM was self-reported daily with eDiary and paper-forms. HCRU was reported at baseline (retrospectively for previous 6 months) and at monthly visits.

Results
Of the 462 patients (GMB n=232, PBO n=230), baseline mean (±SD) days/month of AHM was 12.3 (±6.0); 44.8% had AHM overuse. The percentage of patients reporting migraine-specific HCRU at baseline in the GMB and PBO groups were respectively: 40% and 50% healthcare-professional visits (HCP), 6% and 5% emergency-room (ER) visits, and in each, 2% hospitalizations. LS mean reductions from baseline in the mean number of days/month with AHM in the DB was greater for the GMB group (3.9 to 4.5 days) compared to PBO (0.4 to 1.0 days) in each of the first 3 months; change difference, -3.1 to -3.5, p<0.001 at each month during Months 1-3. During the OL, reductions from baseline ranged -4.7 to -5.3 days; prior PBO group reductions were comparable to that observed in GMB. During the DB, reductions from baseline of migraine-specific HCP (per 100 person-years) were numerically greater with GMB than PBO (215.5 vs -155.3); during OL, the prior PBO group reductions (212.9) were similar to GMB (222.6). For both groups, migraine-specific ER visits were <13 and hospitalizations were <2 per 100 person-years during the DB and OL.

Conclusions
GMB-treated patients with treatment-resistant migraine had clinically meaningful reductions in days with AHM and numerically greater reductions in migraine-specific HCP. The abstract was previously presented at EHF (2020).

Keywords: Acute Headache Medication Use, Health Care Resource Utilization, Treatment-Resistant Migraine