Objective: To investigate the efficacy of galcanezumab in episodic migraine (EM) by subgroups of low- versus high-frequency of migraine headaches.

Background: Migraine is a neurological disorder with high disease burden and unmet clinical need.

Design/Methods: Data were pooled from two phase 3 randomized trials. Headaches were tracked via an electronic patient-reported outcome system, and randomization was stratified by low-frequency (LFEM; 4-7 monthly migraine headache days [MHD]) or high-frequency (HFEM; 8-14 monthly MHD). Subgroup analysis of efficacy data, including functional impact and disability measures, were conducted for LFEM and HFEM subgroups with a linear or generalized linear mixed model repeated measures approach.

Results: For intent-to-treat patients (N=1773), mean age was 41.3 years, majority were white (75%), female (85%), and HFEM was present in 66% of patients. There were no statistically significant (p<0.05) subgroup-by-treatment interactions for all measures. In both the LFEM and HFEM subgroups, the least square mean change differences from baseline in monthly MHDs and monthly MHDs with acute medication use compared with placebo were statistically significantly reduced for galcanezumab 120-mg and 240-mg. In both LFEM and HFEM subgroups, the mean percentage of patients with ≥50%, ≥75%, and 100% reduction from baseline in overall monthly MHDs during treatment was statistically significantly greater in both galcanezumab dose-groups compared with placebo (p<0.001). Galcanezumab treatment statistically significantly improved the Migraine-Specific Quality of Life Questionnaire (MSQ) role function-restrictive domain score compared to placebo (p<0.001) and the migraine disability assessment (MIDAS) total score compared with placebo (p≤0.001) for patients in both LFEM and HFEM subgroups.

Conclusions: Overall, treatment effects of both doses of galcanezumab were similar with regard to reduction in monthly MHD, improved functioning, and reduced disability for both LFEM and HFEM subgroups. The percentage of patients with ≥50%, ≥75%, and 100% reduction from baseline in MHDs were similar between LFEM and HFEM subgroups.