A Placebo-Controlled Study of Galcanezumab in Patients with Episodic Cluster Headache: Results from the 8-Week Double-Blind Treatment Phase

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Objective: To assess the efficacy and safety of galcanezumab in individuals with episodic cluster headache (CH).

Background: Patients with episodic CH experience recurrent intense, unilateral headache “attacks” with cranial autonomic symptoms and/or restlessness. Efficacious treatments that reduce attack frequency remain an unmet need.

Design/Methods: This study comprised four periods: screening; prospective baseline; 8-week, double-blind, placebo-controlled treatment; and washout. We present results from the double-blind treatment period. Participants were randomized 1:1 to galcanezumab 300 mg (N=49) or placebo (N=57) subcutaneously (SC) once monthly. The primary endpoint was overall mean change from baseline in weekly CH attack frequency across Weeks 1-3. The key secondary endpoint was the proportion of participants achieving a reduction from baseline of ≥50% in weekly CH attack frequency at Week 3.

Results: The mean change in weekly CH attack frequency across Weeks 1-3 was -8.7 for galcanezumab versus -5.2 for placebo (treatment groups difference in mean change, -3.5 [95% CI -6.7, -0.2]; p=0.036). The percentage of participants achieving ≥50% reduction in weekly CH attack frequency at Week 3 was 76% for galcanezumab versus 57% for placebo (p=0.04). Four participants (8%) in the galcanezumab group discontinued during the double-blind period versus 12 (21%) in placebo. In the placebo group, 8 (14%) discontinued due to lack of efficacy versus 1 (2%) with galcanezumab (p=0.036). There were no clinically meaningful differences between treatment groups on tolerability or safety parameters except for a greater incidence of injection site pain with galcanezumab versus placebo (8.2% vs 0%, p=0.043).

Conclusions: Galcanezumab reduced the weekly CH attack frequency across Weeks 1-3 and resulted in a greater percentage achieving a ≥50% reduction in the weekly CH attack frequency at Week 3. The safety profile of galcanezumab in this population was similar to that seen previously in patients with episodic or chronic migraine.