AAN 75th ANNUAL MEETING ABSTRACT

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Abstract Title: Atogepant for the Preventive Treatment of Migraine Among Participants With Episodic Migraine With Prior Treatment Failure: Results From the ELEVATE Trial

Press Release Title: New Drug May Help Prevent Migraine for Difficult Cases

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Objective: To evaluate the efficacy, safety, and tolerability of atogepant 60 mg once daily (QD) for the preventive treatment of episodic migraine (EM) in participants who have previously failed 2 to 4 classes of oral preventive medications.

Background: Atogepant, an oral calcitonin gene-related peptide receptor antagonist, is approved for the preventive treatment of EM in adults in the United States.

Design/Methods: ELEVATE was a randomized, double-blind, placebo-controlled trial conducted in Europe and North America. Adults (18-80 years) who previously failed 2-4 classes of conventional oral medications for migraine prevention and reported 4-14 monthly migraine days (MMDs) during the 28-day screening period were randomized to treatment with atogepant 60 mg QD or placebo. The primary endpoint was the change from baseline in mean MMDs across 12 weeks. Secondary endpoints included achievement of ≥50% reduction in MMDs, change from baseline in mean monthly headache days, and change from baseline in acute medication use days across 12 weeks.

Results: A total of 309 participants were included in the efficacy analysis population (placebo: n=155; atogepant 60 mg QD: n=154). Of these participants, 56.0% failed 2 classes of oral migraine preventive medications and 44.0% failed ≥3 classes. A significantly greater decrease in MMDs (mean [standard error]) across the 12-week treatment period was observed with atogepant 60 mg QD (−4.20 [0.39]) vs placebo (−1.85 [0.39]; P<0.0001). All secondary endpoints demonstrated statistically significant improvement with atogepant vs placebo across the 12-week treatment period. The most commonly (≥5%) reported treatment-emergent adverse events (atogepant vs placebo, respectively) included constipation (10.3% vs 2.5%), COVID-19 (8.3% vs 9.6%), nausea (7.1% vs 3.2%), and nasopharyngitis (5.1% vs 7.6%).

Conclusions: Atogepant 60 mg QD was efficacious, safe, and well-tolerated for the preventive treatment of EM in participants who previously failed 2-4 classes of oral preventive migraine medications.

Study Support: AbbVie