Abstract Title: Efficacy and safety of erenumab in episodic migraine patients with 2–4 prior preventive treatment failures: Results from the Phase 3b LIBERTY study

Press Release Title: When Others Fail, New Migraine Treatment May Work

Objective: To assess the efficacy and safety of erenumab in patients with episodic migraine who have failed 2–4 prior preventive migraine treatments (PMTs).

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Background: Erenumab is a fully human monoclonal antibody that inhibits the canonical CGRP receptor. Clinical studies have demonstrated the efficacy and safety of erenumab in patients with episodic and chronic migraine. Current oral preventive therapies are associated with low adherence rates due to the lack of efficacy and/or poor tolerability. It is therefore important to assess the safety and efficacy of erenumab in patients who have failed multiple therapies.

Design/Methods: LIBERTY (NCT03096834) was a 12-week, double-blind, randomized study. Patients (N=246) were randomized (1:1) to receive erenumab 140mg and placebo. The primary endpoint was the proportion of patients achieving ≥50% reduction in mean monthly migraine days (MMDs) during Weeks 9–12 (Month 3). Secondary endpoints included change from baseline to Month 3 in MMDs and monthly acute migraine-specific medication days (MSMDs) and safety/tolerability.

Results: At baseline, proportion of patients who failed 2, 3, and 4 prior PMTs were 38.6%, 37.8%, and 22.8%, respectively. The mean (SD) MMDs and MSMDs were 9.3 (2.64) and 4.6 (2.89), respectively. At week 12, the proportion of patients achieving ≥50% reduction in MMD was higher in those treated with erenumab 140mg vs placebo (30.3% vs 13.7%; OR [95% CI]: 2.73 [1.43, 5.19]; p=0.002). At week 12, there were greater reductions in MMDs and MSMDs with erenumab 140mg vs placebo (mean difference [95% CI] in MMD: −1.61 [−2.70, −0.52]; p=0.004; mean difference (95% CI) in MSMD: −1.73 [−2.46, −1.01]; p<0.001). Safety and tolerability profile of erenumab was comparable to placebo. No patients in the erenumab group discontinued due to adverse events.

Conclusions: These results confirm the efficacy and safety of erenumab in this first dedicated study of a difficult to treat population with 2–4 prior preventive migraine treatment failures.

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