

Consistent efficacy and safety of erenumab over time in patients with episodic migraine who completed a 5-year, open-label extension study

Messoud Ashina,¹ Peter J Goadsby,² Uwe Reuter,³ Stephen Silberstein,⁴ David W. Dodick,⁵ Feng Zhang,⁶ Fei Xue,⁶ Sunfa Cheng,⁶ Denise E. Chou,⁶ Gabriel Paiva da Silva Lima⁶

¹Department of Neurology, Danish Headache Center, Rigshospitalet Glostrup, Faculty of Health and Medical Sciences, University of Copenhagen, Denmark; ²NIHR-Wellcome Trust King's Clinical Research Facility, King's College London, London, UK; ³Department of Neurology, Charité Universitätsmedizin Berlin, Berlin, Germany; ⁴Jefferson Headache Center, Thomas Jefferson University, Philadelphia, PA; ⁵Department of Neurology, Mayo Clinic, Scottsdale, AZ; ⁶Amgen Inc., Thousand Oaks, CA.

One sentence summary: Consistent efficacy and safety of erenumab over 5 years in patients with episodic migraine.

Background: Erenumab demonstrated significant reduction in migraine frequency in previous short-term studies; however, long-term data are not available. The objective of the current study (NCT01952574) was to evaluate the long-term efficacy and safety of erenumab in patients with episodic migraine who completed a 5-year open-label treatment phase (OLTP).

Methods: Following a 12-week placebo-controlled, double-blind treatment phase (DBTP), 383 patients continued in the OLTP, receiving erenumab 70 mg every 4 weeks, and increasing to 140 mg after a protocol amendment (after ~2 years in OLTP). A separate protocol amendment was implemented to resume efficacy data collection in years 4–5. A total of 214 patients completed the 5-year OLTP; 138 patients had efficacy data at week 268 (end of 5-year OLTP) and were included in this analysis.

Results: Mean (SD) change in monthly migraine days (MMD) from DBTP baseline of 8.5 (2.5) days was -4.8 (3.9) at week 64 (mean of last 4 weeks of 1-year OLTP; N=130), and -5.3 (3.9) at week 268 (mean of last 4 weeks of 5-year OLTP). The percentage of patients achieving MMD response at weeks 64/268 was 62%/71% for achievement of $\geq 50\%$ reduction; 41%/47% for $\geq 75\%$ reduction; and 26%/36% for 100% reduction. Among acute migraine-specific medication (AMSM) users at baseline (6.2 [2.7] treatment days/month), mean (SD) change in AMSM days was -3.2 (3.4) at week 64 and -4.4 (3.3) at week 268. Clinically meaningful improvements were observed in HIT-6TM: 68%/73% of patients achieved ≥ 5 -point reduction from baseline at weeks 64/268. The exposure-adjusted patient incidence of AEs and serious AEs during the OLTP was 91.6 and 2.8 per 100 subject-years, respectively; this was lower than that observed for erenumab 70 mg treatment arm during the DBTP. One fatality (“death unattended”) occurred during the safety follow-up period when no erenumab was administered and was considered unrelated to study drug by the investigator.

Conclusions: Patients receiving erenumab through 5 years of treatment demonstrated a consistent and sustained response. In this subgroup analysis of patients who completed the 5-year study, no new safety concerns were identified.