

Consistent efficacy and safety of erenumab in episodic migraine patients during a 5-year, open-label extension study

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Introduction:

Erenumab demonstrated significant reduction in migraine frequency in short-term studies; however, long-term data are not available. The long-term efficacy and safety of erenumab was evaluated in episodic migraine patients who completed a 5-year open-label treatment phase (OLTP; NCT01952574).

Methods:

Following a 12-week placebo-controlled, double-blind treatment period (DBTP), 383 patients continued into the OLTP, receiving erenumab 70mg every 4 weeks, and increasing to 140mg after a protocol amendment (after ~2 years in OLTP). Overall, 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:

At Week 268, the mean(SD) change from the DBTP baseline in monthly migraine days (MMD) and monthly acute migraine-specific medication (AMSM) days was -5.3(3.9) and -4.4(3.3), respectively (Table 1). The proportion of patients who achieved $\geq 50\%$, $\geq 75\%$ and 100% reduction in MMD at Week 64/268 was 62%/71%, 41%/47%

and 26%/36%, respectively. Clinically meaningful improvements were observed in headache impact test-6TM: 68%/73% of patients achieved ≥ 5 -point reduction from baseline at Weeks 64/268. Exposure-adjusted patient incidence of adverse events (AEs) and serious AEs during OLTP was 91.6 and 2.8 per 100 subject-years, respectively; this was lower than that observed for erenumab 70mg during DBTP. One fatality occurred during the safety follow-up period \rightarrow when no erenumab was administered and was considered unrelated to study drug by the investigator.

Conclusion:

Patients receiving erenumab over 5-years demonstrated consistent and sustained response. Safety was comparable to that observed in patients who received erenumab 70mg during the randomised phase of the trial.

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