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Long-term safety and tolerability of erenumab in episodic migraine: A pooled analysis from two clinical trials and their extension phases

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Objective: To assess the long-term safety of erenumab using pooled data from the double-blind treatment phases (DBTP) and open-label extension phases (OLEP) of two clinical trials in episodic migraine (NCT03096834, NCT01952574).

Background: Erenumab has demonstrated significant reduction in migraine frequency and improved quality of life; however, more long-term safety data are important for clinical decision making.

Design/Methods: The incidence of adverse events (AEs) were summarized as exposure-adjusted patient incidence rates per 100 patient-years (r). Anti-erenumab antibodies were detected using a validated bridging electrochemiluminescence immunoassay.

Results: Of 729 patients randomized across both studies, 502 received erenumab (70 or 140 mg) or placebo in the 12-week DBTP and 623 received erenumab (70 or 140 mg) in the 3- or 5-year OLEP. The cumulative duration of exposure to erenumab during the DBTP and OLEP was 54.3 and 1899.5 patient-years, respectively. Overall exposure-adjusted AE incidence rates were similar in the placebo and erenumab groups during the DBTP (357.5 vs 345.1/100 patient-years; no new AEs emerged over time during the OLEP (176.1/100 patient-years). The most common AE for the erenumab treatment groups (presented as n [r], whereby n = number of subjects reporting ≥1 AE) was nasopharyngitis (DBTP, 11 [20.9]; OLEP, 224 [24.0]). The incidence of constipation (DBTP: 4 [7.5]; OLEP: 40 [3.2]) and hypertension (DBTP: 3 [5.6]; OLEP: 46 [3.7]) remained low over time. The occurrence of anti-erenumab antibodies was 5.8% in the DBTP and 10.3% in the OLEP, with a respective 0.4% and 1.4% developing neutralizing antibodies.

Conclusions: Erenumab demonstrated a consistent favorable safety and tolerability profile with long-term exposure.