Three-Year Efficacy and Safety of Erenumab in Participants with Episodic Migraine and 2–4 Prior Preventive Treatment Failures: Results from the LIBERTY Study

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OBJECTIVE

To report the efficacy and safety of erenumab 140 mg at completion of the LIBERTY study (NCT03096834).

BACKGROUND

Erenumab (erenumab-aooe in US) is a fully human monoclonal antibody targeting the canonical calcitonin gene-related peptide receptor for the prevention of migraine. The double-blind treatment phase (DBTP) of LIBERTY demonstrated efficacy of erenumab 140 mg in patients with episodic migraine (EM) failing 2−4 prior preventive treatments**.** Interim analyses demonstrated that efficacy was maintained throughout first and second years of the open-label extension phase (OLEP)**.**

METHODS

Patients completing DBTP (N=240) continued into OLEP, receiving monthly erenumab 140 mg for ≤3 years; a subset of patients (N=36) entered post-trial access (PTA) for ≤6 months. Outcomes

measured at week 168 were achievement of ≥30%, ≥50%, ≥75%, and 100% reduction in monthly migraine days (MMDs) from baseline; change from baseline in MMD, Headache Impact Test (HIT-6™) total score, Migraine Physical Function Impact Diary (MPFID) Everyday Activities (EA), Physical Impairment (PI), and safety.

RESULTS

Of 240/246 (97.6%) patients entering OLEP (118 continuing erenumab, 122 switching from placebo), 169 (70.4%) completed the 3-year OLEP; all 36 (15.0%) completed PTA. Discontinuations were mainly due to lack of efficacy (12.5%, n=30), patient decision (10.8%, n=26), and adverse events (AEs; 4.6%; n=11, single case per AE). The ≥30%, ≥50%, ≥75%, and 100% responder rates at 3-year completion were 72.8%, 52.3%, 33.1%, and 13.2%, respectively. Mean (SD) change in MMD from baseline at 3-year completion was −4.4 (3.9). Mean (SD) change in HIT-6, MPFID-EA, and MPFID-PI scores from baseline at 3-year completion was –9.7 (8.9), –6.1 (8.2) and –5.1 (7.6), respectively. Common AEs (>10%) were nasopharyngitis, influenza, and back pain.

CONCLUSIONS

Efficacy was sustained over 3 years in patients with EM and 2–4 prior non successful migraine preventive therapies. Erenumab was well-tolerated, with no new safety signals reported after three years exposure.

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SCIENTIFIC RELEVANCE

LIBERTY is a phase 3b, multicenter, randomized 12-week, double-blind, placebo-controlled study with 3-year open-label extension phase and a 6 month post-trial access phase in a sub-set of patients evaluating the safety and efficacy of erenumab in patients with episodic migraine (EM) who failed 2–4 prior preventive treatments for migraine. This study reported the efficacy and safety of erenumab at completion of the study and showed that efficacy was sustained over 3 years in patients with difficult-to-treat EM. In addition, erenumab was well-tolerated with no new

safety findings after long-term exposure. Data from this study, in addition to data from the previous phase 2/3 studies, provide valuable information for clinicians treating patients with migraine, especially for those patients, with limited treatment options.

PRACTICE GAP

The LIBERTY trial is the only phase 3b anti-CGRP study that demonstrated the long-term safety and efficacy in patients with EM in whom 2–4 prior preventive treatments have failed. The results add to the consistent body of evidence for erenumab across the full spectrum of patients with migraine, from treatment-naive patients to those for whom 2–4 prior preventive treatments had failed.

Disclosures:

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Michel D Ferrari reports no competing interests.

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