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Sustained Efficacy and Safety of Erenumab in Patients with Episodic Migraine who Failed 2–4 Prior Preventive Treatments: 2-year Interim Results of the LIBERTY Open-label Extension Study

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Background and Methods

Introduction

- Erenumab is a fully human monoclonal antibody that selectively targets and blocks the canonical calcitonin gene-related peptide receptor[1]
- The double-blind treatment phase (DBTP) of the LIBERTY study (NCT03096834) demonstrated efficacy of erenumab 140 mg in patients with episodic migraine (EM) who had failed 2–4 prior preventive treatments[2]. The 3-year open-label extension phase (OLEP) of the LIBERTY study is ongoing

Objective

- The efficacy and safety of erenumab at Week 112 of the 3-year OLEP of the LIBERTY study is presented here

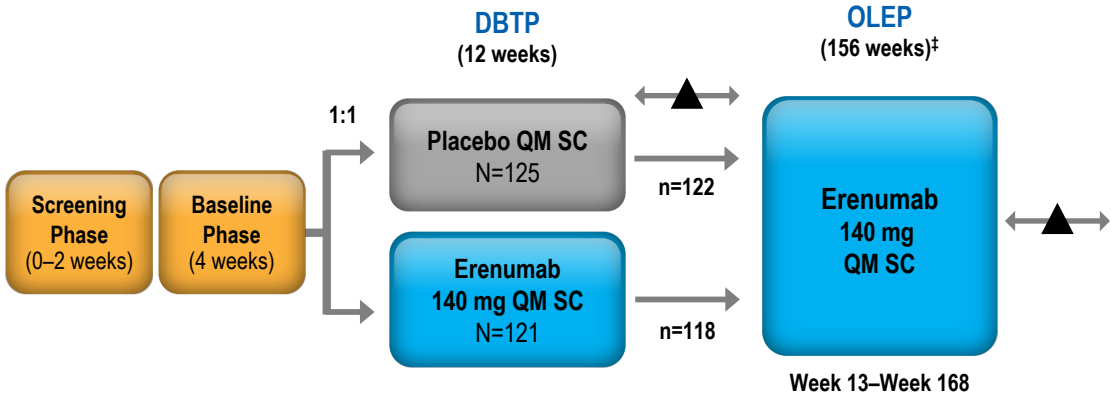
Eligibility criteria

- Patients with EM (4–14 migraine days/month) who had failed 2–4 prior preventive treatments were randomised (1:1) to either placebo or once-monthly subcutaneous erenumab 140 mg and treated for 12-week DBTP3
- Patients completing the DBTP of the LIBERTY study were enrolled into the OLEP for 3 years (156 weeks) and both arms received erenumab 140 mg

Outcomes measured through Week 112

- Achievement of ≥50%, ≥75%, 100% reduction in MMD compared to the DBTP baseline
- Change in MMD from the DBTP baseline
- Change in HIT-6, MPFID-EA and MPFID-PI scores from the DBTP baseline
- Reporting of AEs

Figure 1. Study design



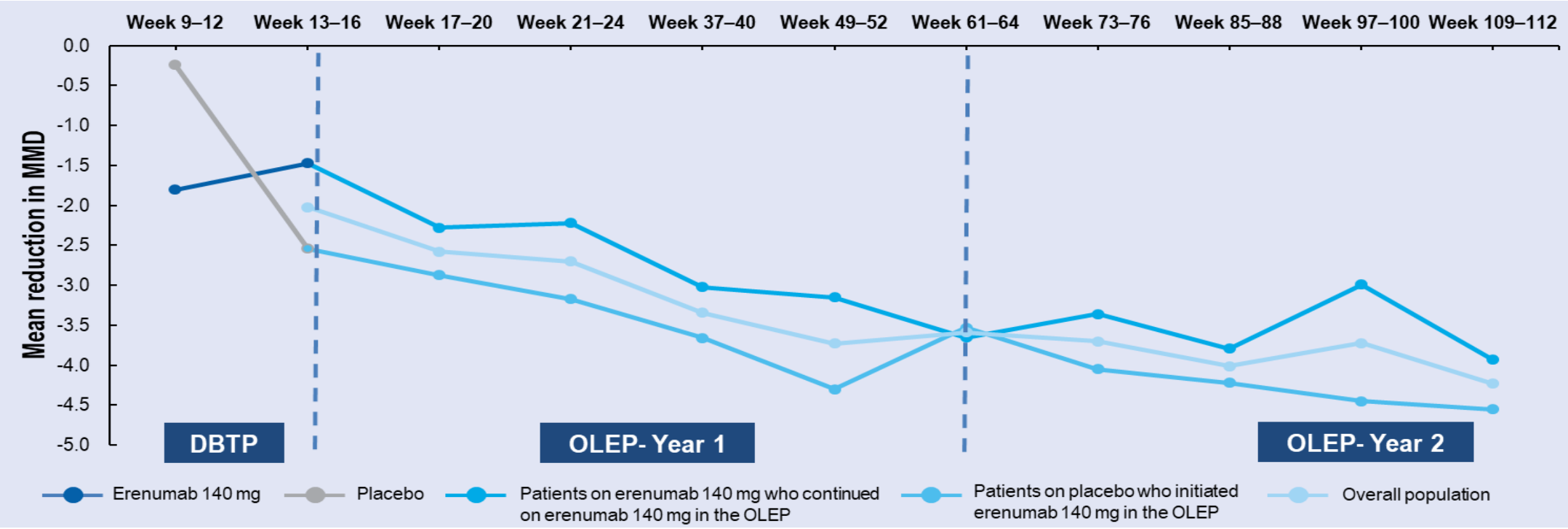
Follow-up phase 16 weeks after the last dose of the study drug. ‡The open-label extension phase is ongoing. DBTP, double-blind treatment phase;

AE, adverse event; DBTP, double-blind treatment phase; EA, everyday activities; EM, episodic migraine; HIT-6TM, Headache Impact Test; MMD, monthly migraine days; MPFID, migraine physical function impact diary; OLEP, open-label extension phase; PI, physical impairment; QM, once a month; SC, subcutaneous;

1. Shi L, et al. *J Pharmacol Exp Ther.* 2016;356:223–31; 2. Reuter U, et al. Lancet. 2018;392:2280–87.

Results

Figure 1. Change in MMD from Baseline until Week 112 of the OLEP



Change in MMD from baseline of the Overall population (N) by visit

Week 9–12	Week 13–16	Week 17–20	Week 21–24	Week 37–40	Week 49–52	Week 61–64	Week 73–76	Week 85–88	Week 97–100	Week 109–112
−1.0, N=237	−2.0, N=237	−2.6, N=235	−2.7, N=227	−3.3, N=205	−3.7, N=187	−3.6, N=137	−3.7, N=187	−4.0, N=182	−3.7, N=179	−4.2, N=173

The mean reduction in monthly migraine days from double-blind treatment phase baseline was sustained over 2 years across all the treatment groups in the open-label extension phase

DBTP, double-blind treatment phase; MMD, monthly migraine days; OLEP, open-label extension phase

Results and Conclusions

Table 2: The Exposure-Adjusted Patient rates of AEs per 100 Patient-Years in the OLEP (open-label analysis set)

Event	Patients on erenumab 140 mg who continued on erenumab 140 mg in the OLEP, N=118, n (%) / e [r]	Patients on placebo who initiated erenumab 140 mg in the OLEP, N=122, n (%) / e [r]	Overall population, N=240 n (%) / e [r]
Any AE	97 (82.2) / 61.5 [157.6]	110 (90.2) / 43.0 [255.7]	207 (86.3) / 104.6 [198.0]
Any SAE	11 (9.3) / 199.3 [5.5]	14 (11.5) / 199.1 [7.0]	25 (10.4) / 398.4 [6.3]
Any AE leading to discontinuation of treatment	4 (3.4) / 209.8 [1.9]	5 (4.1) / 213.1 [2.3]	9 (3.8) / 422.9 [2.1]
All serious treatment-emergent AEs	11 (9.3) / 199.3 [5.5]	14 (11.5) / 199.1 [7.0]	25 (10.4) / 398.4 [6.3]
Any treatment-related AE	21 (17.8) / 175.8 [11.9]	45 (36.9) / 158.4 [28.4]	66 (27.5) / 334.2 [19.8]

N, number of patients in the analysis set; n, number of patients reporting at least one occurrence of an adverse event in that class; e, sum across all patients, the total time at risk in the OLEP in years; r=exposure-adjusted subject rate per 100 patient-years (n/e*100). MedDRA Version 22.1 has been used for the reporting of adverse events. Preferred terms are sorted in descending frequency of AEs in the 'Overall population' column.

The most frequently reported treatment-emergent adverse events (per 100 patient-years) were nasopharyngitis, influenza and back pain

Conclusion

- Efficacy of Erenumab was sustained throughout 2 years of treatment with Erenumab 140 mg in a difficult-to-treat patient population with 2–4 prior preventive treatment failures
- Erenumab was well tolerated and reported safety was aligned with the known safety profile

AE, adverse events; OLEP, open-label extension phase; SAE, serious adverse events