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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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**Aim**:The LIBERTY study (NCT03096834) demonstrated efficacy of erenumab 140mg in episodic migraine (EM) patients with 2–4 prior preventive treatment failures (PPTF). We assessed the efficacy and safety of erenumab at Week 112 of the 3-year open-label treatment phase (OLTP) of the LIBERTY study.**Methods**:Patients completing the 12-week double-blind treatment phase (DBTP) of the LIBERTY study (N=240) initially randomised to placebo and erenumab 140mg (1:1) were enrolled into the OLTP to receive OL treatment with monthly erenumab 140mg for 3 years. Outcomes measured included proportion of patients who achieved ≥50%/≥75%/100% reduction from the DBTP baseline in monthly migraine days (MMD), change from the DBTP baseline in MMD, Headache Impact Test total score, Migraine Physical Function Impact Diary (Everyday Activities and Physical Impairment) scores and safety.**Results**:Detailed results are presented in **Table 1**. Both patients groups: on continuous erenumab and those who initiated erenumab in the OLTP, demonstrated improvement through 2 years of treatment similar to what was reported at 1 year. The responder rates refer to a cross sectional interindividual observation and not a longitudinal intraindividual responder rate. The change in MMD from DBTP baseline in the overall group sustained over 2 years (1 year [52 weeks]: −3.7[4.1]; 2 year [112 weeks]: −4.2[5.0]). The median (Q1, Q3) erenumab exposure (during OLTP) was 106 (103.8, 106.1) weeks. Nearly 86.3% (overall group), 82.2% (continuing erenumab) and 90.2% (initiating erenumab) of patients reported adverse events (AEs) in OLTP. The most frequently reported AEs/100 patient-years during OLTP were nasopharyngitis (33.9), influenza (10.3), and back pain (6.6). No deaths were reported.**Conclusions**:Long-term treatment with erenumab showed sustained reductions in migraine frequency in EM patients with 2–4 PPTF both in patients continuously treated with erenumab and those initiating erenumab during the OLTP. Erenumab was well tolerated with no new safety signals.

## Figure 1

**Table 1. Efficacy outcome measures at the end of the second year of the OLTP, Observed (Open-Label Analysis Set)**

| Outcomes | Values at Week 112 of OLTP | | | | | |
|---|---|---|---|---|---|---|
| | Patients on erenumab 140 mg continued on erenumab 140 mg in the OLTP, N=118 | | Patients on placebo who initiated erenumab 140 mg in the OLTP, N=122 | | Overall population, N=240 | |
| | n | | n | | n | |
| ≥50% reduction in MMD | 88 | 47 (53.4%) | 85 | 52 (61.2%) | 173 | 99 (57.2%) |
| ≥75% reduction in MMD | 88 | 26 (29.5%) | 85 | 27 (31.8%) | 173 | 53 (30.6%) |
| 100% reduction in MMD | 88 | 13 (14.8%) | 85 | 15 (17.6%) | 173 | 28 (16.2%) |
| Change from the DBTP baseline in MMD | 88 | −3.9 (5.5) | 85 | −4.6 (4.6) | 173 | −4.2 (5.0) |
| Change from the DBTP baseline in HIT-6 | 91 | −8.5 (8.0) | 90 | −10.4 (9.3) | 181 | −9.5 (8.7) |
| Change from the DBTP baseline in MPFID-PI | 88 | −4.1 (9.1) | 86 | −5.0 (11.4) | 174 | −4.5 (10.3) |
| Change from the DBTP baseline in MPFID-EA | 88 | −4.9 (9.7) | 86 | −6.0 (10.9) | 174 | −5.4 (10.3) |

Data are mean (SD) or n (%) of the patients with non-missing value at Week 112; data for HIT-6 reported at Week 108; n=number of patients with a value at both baseline and that time point.

Change from baseline = post-baseline−baseline. The baseline period is defined as the period between Week-4 visit and the day prior to first dose

DBTP, double-blind treatment phase; HIT-6, Headache Impact Test; MMD, monthly migraine days; MPFID-EA; Migraine Physical Function Impact Diary-everyday activities; MPFID-PI, Migraine Physical Function Impact Diary-physical impairment; N, number of subjects included in the analysis set; OLTP, open-label treatment phase; SD, standard deviation