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Three-year efficacy and safety of erenumab in participants with episodic migraine and 2–4 prior preventive treatment failures: Results from the LIBERTY study

Reuter U.[1,2], Goadsby P. [3,4], Ferrari M. [5], Paiva da Silva Lima G. [6], Mondal S. [7], Wen S. [8], Stites T. [8], Arkuszewski M. [9], Lanter-Minet M. [10,11], Pandhi S. [9]
[1]Charité Universitätsmedizin Berlin, Neurology, Berlin, Germany
[2]Universitätsmedizin Greifswald, Greifswald, Germany
[3]King's College , NIHR-Wellcome Trust, London, United Kingdom
[4]University of California, Neurology, Los Angeles, United States
[5]Leiden University Medical Center, Neurology, Leiden, Netherlands
[6]Amgen Inc., Thousand Oaks, United States
[7]Novartis Healthcare Pvt. Ltd., Hyderabad, India
[8]Novartis Pharmaceutical Corporation, East Hanover, United States
[9]Novartis Pharma AG, Basel, Switzerland
[10]Université Côte d'Azur, Pain Department and FHU InovPain, Nice, France
[11]Auvergne University, INSERM U1107 Migraine and Trigeminal Pain, Clermont-Ferrand, France

OBJECTIVE

Efficacy of erenumab 140mg has been demonstrated in the 12-week double-blind treatment phase (DBTP) of the LIBERTY study. Efficacy and safety of erenumab at completion of the 3-year open-label extension phase (OLEP) are reported.

METHODS

Patients completing the DBTP (N=240) continued into OLEP, receiving monthly erenumab 140mg for ≤3 years. Outcomes measured at Week 168 were ≥50% and ≥75% reduction in monthly migraine days (MMD); change from baseline (BL) 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 3-year OLEP. 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 ≥50% and ≥75% responder rate at 3-year completion was 52.3% and 33.1% (Table). Mean (SD) change from BL at 3-year completion was −4.4 (3.9) in MMD. Mean (SD) change from BL at 3-year completion was –9.7 (8.9), –6.1 (8.2) and –5.1 (7.6) for HIT-6, MPFID-EA and -PI scores. Common AEs (>10%) were nasopharyngitis, influenza and back pain.

CONCLUSIONS

Efficacy was sustained over 3 years in patients with difficult-to-treat EM who failed 2–4 prior migraine preventives. Erenumab was well-tolerated, with no new safety signals reported after long-term exposure.

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Figure 1

Table. Efficacy outcomes at Week 168 of the OLEP (open-label analysis set)

Outcomes	Patients on erenumab 140 mg who continued erenumab 140 mg in the OLEP, N=118		Patients on placebo who initiated erenumab 140 mg in the OLEP, N=122		Overall population, N=240	
Reduction in MMD	**m**	**n (%)**	**m**	**n (%)**	**m**	**n (%)**
≥30%	77	52 (67.5)	74	58 (78.4)	151	110 (72.8)
≥50%	77	41 (53.2)	74	38 (51.4)	151	79 (52.3)
≥75%	77	23 (29.9)	74	27 (36.5)	151	50 (33.1)
100%	77	11 (14.3)	74	9 (12.2)	151	20 (13.2)
Change from DBTP BL in	**m**	**Mean (SD)**	**m**	**Mean (SD)**	**m**	**Mean (SD)**
MMD	77	–4.3 (3.8)	74	–4.5 (4.0)	151	–4.4 (3.9)
HIT-6™*	75	–8.5 (8.7)	76	–10.8 (9.0)	151	–9.7 (8.9)
MPFID-PI	77	–5.5 (6.7)	74	–4.6 (8.5)	151	–5.1 (7.6)
MPFID-EA	77	–6.8 (7.0)	74	–5.3 (9.3)	151	–6.1 (8.2)

*Data for HIT-6 reported at Week 164.
Data are n (%) or mean (SD) of patients with non-missing value at Week 168.
Change from baseline = post-baseline−BL. The BL period is defined as the period between Week-4 visit and the day prior to first dose. The BL value is the prorated number to 28-day equivalents during BL period. At each time point, only patients with a value at both BL and that time point are included.
BL, baseline; DBTP, double-blind treatment phase; EA, everyday activities; HIT-6, Headache Impact Test; m, the total number of patients in the treatment group with observed data at Week 168 (Week 164 for HIT-6); MMD, monthly migraine days; MPFID; Migraine Physical Function Impact Diary; N, number of patients included in the analysis set; n, number of patients who responded; OLEP, open-label extension phase; PI, physical impairment; SD, standard deviation.

Conflict of interest

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