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Effect of Erenumab on Patient-reported Outcomes in Patients with Episodic Migraine from Asia, the Middle East and Latin America: The EMPOwER Study

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Introduction: The EMPOwER study (NCT03333109) demonstrated the efficacy of erenumab 140 mg and 70 mg over placebo in reducing migraine frequency over 3 months in patients with episodic migraine from Asia, the Middle East and Latin America. Here, we analysed the effects of erenumab on patient-reported outcomes (PROs) assessing the function and quality-of-life outcomes after 3 months of treatment.
Objectives: To evaluate the effect of erenumab on PROs in the EMPOwER study.
Methods: Patients (N=900) were randomised (2:3:3) to subcutaneous injections of erenumab 140 mg, erenumab 70 mg and placebo for 3 months. The study evaluated the mean change from baseline in Headache Impact Test (HIT-6), Migraine Physical Function Impact Diary (MPFID), modified Migraine Disability Assessment (mMIDAS) and EuroQoL 5-dimensions 5-levels scale (EQ-5D-5L) over 3 months of the double-blind treatment phase.
Table:

Adjusted mean change from baseline in PROs at Month 3 (Full Analysis Set)

Outcome measure	Placebo n, mean (SE)	Erenumab 70 mg n, mean (SE)	Comparison of Erenumab 70 mg vs placebo mean difference (95% CI) p-value¤	Erenumab 140 mg n, mean (SE)	Comparison of Erenumab 140 mg vs placebo mean difference (95% CI) p-value¤

HIT-6	n=308, −6.62 (0.44)	n=296, −8.39 (0.45)	−1.77 (−2.99; −0.56), p=0.004	n=200, −9.34 (0.54)	−2.71 (−4.07; −1.36), p<0.001
mMIDAS	n=308, −6.59 (0.43)	n=294, −8.11 (0.43)	−1.52 (−2.69; −0.35), p=0.011	n=200, −8.99 (0.52)	−2.40 (−3.70; −1.10), p<0.001
MPFID-PI	n=310, −2.31 (0.51)	n=306, −3.95 (0.51)	−1.64 (−3.03; −0.25), p=0.021	n=199, −4.27 (0.63)	−1.96 (−3.53; −0.40), p=0.014
MPFID-EA	n=310, −3.19 (0.50)	n=306, −4.94 (0.50)	−1.75 (−3.10; −0.40), p=0.011	n=199, −5.61 (0.61)	−2.42 (−3.94; −0.90), p=0.002
EQ-5D-5L QoL VAS	n=308, 5.22 (0.78)	n=293, 7.08 (0.79)	1.86 (−0.28; 4.00), p=0.088	n=200, 8.13 (0.96)	2.91 (0.52; 5.29), p=0.017
EQ-5D-5L QoL Index value	n=308, 0.030 (0.004)	n=293, 0.037 (0.004)	0.006 (−0.005; 0.018), p=0.268	n=200, 0.032 (0.005)	0.001 (−0.011; 0.014), p=0.830
	n/M (%)	**n/M** (%)	**OR** (95% CI), p-value[#]	**n/M** (%)	**OR** (95% CI), p-value[#]
MIDAS improvement in disability category[¥]	117/308 (38.0)	162/294 (55.1)	2.0 (1.44; 2.77), p<0.001	104/200 (52.0)	1.78 (1.24; 2.55), p=0.002

[¤]Statistical significance (2-sided) at 0.05 level. [¥]Since mMIDAS scoring is based on 1-month recall period, the original MIDAS disability categories were based on converted mMIDAS scores, calculated as a sum of all three-monthly assessments, representing 3-months recall period. Change to lower disability category after baseline is considered an improvement. n: The number of subjects who responded. M: The total number of subjects in the treatment group with response variable defined. Statistical analysis utilises a Cochran-Mantel-Haenszel (CMH) test adjusting for stratification factor. [#]p-value is reported for unadjusted relative rate and rate difference. CI, confidence interval; EA, Everyday Activity;

EQ-5D-5L, EuroQoL 5-dimension 5-level scale; FAS, full analysis set; mMIDAS, modified MIDAS; MIDAS, Migraine Disability Assessment; MPFID, Migraine Physical Function Impact Diary; OR, odds ratio; PI, Physical Impairment; QoL, quality of life; PROs, patient-reported outcomes: SE, standard error; TD, treatment difference; VAS, visual analog scale; vs, versus.

Results: Results at Month 3 from baseline are presented here:

- At Month 3, greater improvement from baseline in HIT-6 score was observed in both erenumab groups compared to placebo (erenumab 140 mg: −9.34 [p<0.001], 70 mg: −8.39 [p=0.004] and placebo: −6.62)
- Both erenumab groups showed greater improvements from baseline at Month 3 in MPFID scores versus placebo (MPFID-physical impairment scores: erenumab 140 mg: −4.27 [p=0.014], 70 mg: −3.95 [p=0.021] and placebo: −2.31; MPFID everyday activities scores: erenumab 140mg: −5.61 [p=0.002], 70 mg: −4.94 [p=0.011] and placebo: −3.19)
- Greater reductions from baseline at Month 3 in mMIDAS scores were observed in both erenumab groups versus placebo (erenumab 140 mg: −8.99 [p<0.001], 70 mg: −8.11 [p=0.011] and placebo: −6.59)
- The responder rate as per the MIDAS disability category was 52.0% for 140 mg, 55.1% for 70 mg and 38.0% for placebo group. The responder rate refers to the proportion of patients with an improvement in the MIDAS disability category
- Change in EQ-5D-5L quality-of-life visual analogue scale from baseline at Month 3 was greater in both erenumab groups compared to placebo (erenumab 140 mg: 8.13 [p=0.017], 70 mg: 7.08 [p=0.088] and placebo: 5.22). No meaningful differences between the erenumab groups and placebo were noted in the index values

Conclusion: In line with pivotal studies, this analysis of the EMPOwER study showed that both erenumab doses led to clinically meaningful improvements versus placebo on the physical functioning and other aspects of daily activities impacted by headache as assessed by PRO scales in patients with episodic migraine.

References:

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