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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

- Erenumab is the first and only human monoclonal antibody targeting the canonical calcitonin gene-related peptide (CGRP) receptor[1] and has demonstrated efficacy and safety for the preventive treatment of episodic migraine (EM) and chronic migraine (CM) in various studies[1-6]
- The Phase 3 EMPOwER study (NCT03333109) has demonstrated the efficacy of erenumab over placebo in reducing migraine frequency over 3 months in patients with EM from Asia, the Middle East, and Latin America[7]
- The results of the primary analysis (e.g., change in monthly migraine days (MMD), change in monthly acute migraine-specific medication days, change in Headache Impact Test (HIT-6™) scores or achievement of ≥50% reduction in MMD) were reported previously[7]

OBJECTIVE

- The objective of this exploratory analysis was to evaluate the effect of erenumab (140 mg and 70 mg) on patients' function and quality of life (QoL) as measured with patient-reported outcomes (PROs) after 3 months of treatment

METHODS

Study Design

- EMPOwER was a randomised, double-blind, placebo-controlled, parallel-group, Phase 3 study conducted at 83 sites across 11 countries in Asia, the Middle East, and Latin America

Patient population

- Patients (N=900) were randomised (2:3:3) to receive subcutaneous injections of erenumab 140 mg, erenumab 70 mg or placebo for 3 months
- Adults aged 18 to 65 years, with a diagnosis of migraine according to the ICHD-3 and an average of ≥4 to <15 MMD and <15 monthly headache days (MHD) were included in the study

Outcome measures

- This exploratory analysis includes mean change from baseline in Headache Impact Test (HIT-6TM), modified Migraine Disability Assessment (mMIDAS), Migraine Physical Function Impact Diary (MPFID) including 2 subscores such as physical impairment (PI) and everyday activities (EA), and EuroQoL 5-dimension 5-level scale (EQ-5D-5L) after 3 months of treatment

Statistical analysis

- Pairwise comparisons versus placebo using linear mixed-effects repeated measures model based on observed monthly data
- The p-values reported for the exploratory outcomes are intended only as a descriptive measure and should be interpreted with caution

RESULTS

Demographic and baseline characteristics

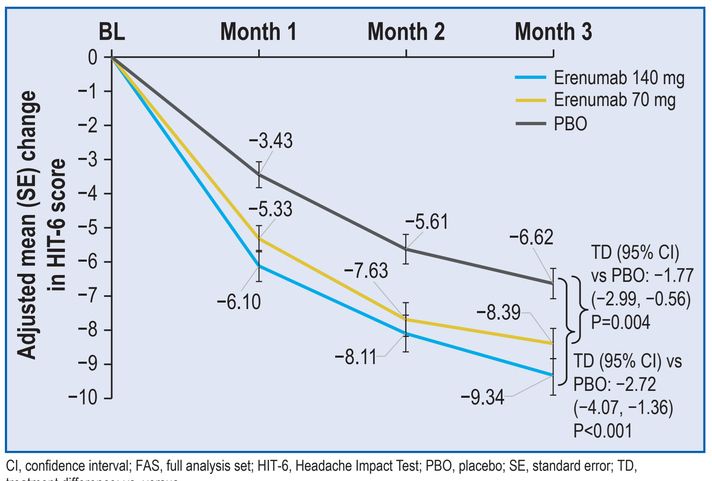
- At baseline, the mean (standard deviation [SD]) age of patients treated in the study was 37.5 (9.9) years and the majority (81.9%) were female
- The mean (SD) MMD for erenumab 140 mg was 8.27 (3.14) days and 8.09 (2.62) days for 70 mg compared to 8.35 (2.76) days for placebo
- The mean (SD) MHD for erenumab 140 mg was 9.53 (3.89) days and 9.15 (2.67) days for 70 mg compared to 9.23 (2.79) days for placebo
- At baseline, PRO scores did not differ significantly between treatment groups

Patient-reported outcomes:

HIT-6 score – Change at Month 3 from baseline

- At Month 3, there was a statistically significant reduction from baseline in mean HIT-6 total score for erenumab 140 mg (−9.34, difference: −2.72, P<0.001) and 70 mg (−8.39, difference: −1.77, P=0.004) compared with placebo (−6.62) (**Figure 1**)

Figure 1. Adjusted mean change from baseline in HIT-6 total score by visit (FAS)

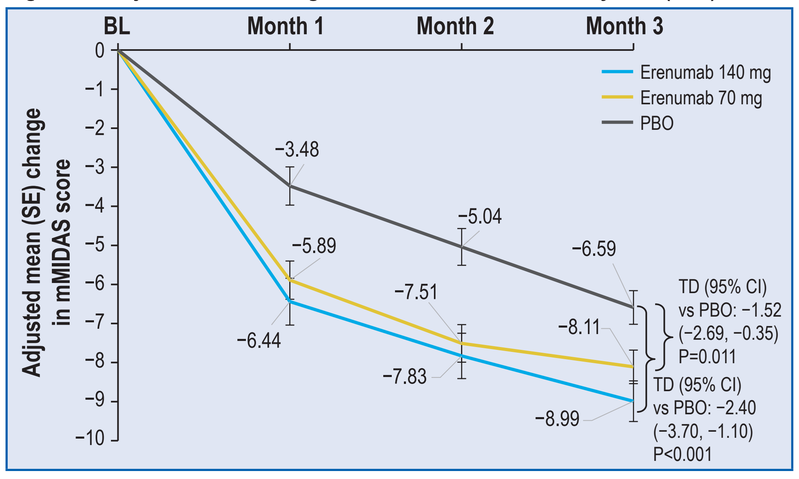


CI, confidence interval; FAS, full analysis set; HIT-6, Headache Impact Test; PBO, placebo; SE, standard error; TD, treatment difference; vs, versus

mMIDAS and converted MIDAS* – Change at Month 3 from baseline

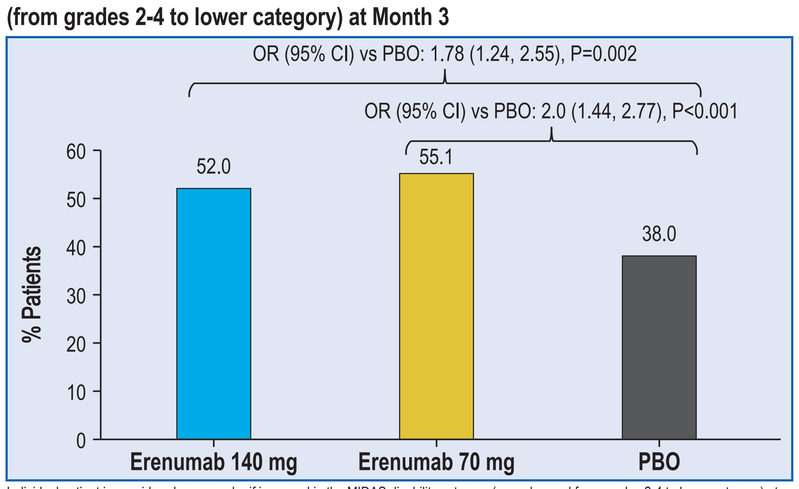
- At Month 3, both erenumab groups had a statistically significant reduction from baseline in mMIDAS scores (140 mg: −8.99, difference: −2.40 [P<0.001], 70 mg: −8.11, difference: −1.52 [P=0.011]) compared to placebo (−6.59) (**Figure 2a**)

Figure 2a. Adjusted mean change from baseline in mMIDAS by visit (FAS)



- Proportions of patients with any improvement in the MIDAS disability category (e.g., grades 2-4 to lower category) were 52.0% for 140 mg, 55.1% for 70 mg and 38.0% for placebo group (**Figure 2b**)

Figure 2b. Proportions of patients with improved MIDAS disability categories (from grades 2-4 to lower category) at Month 3



Individual patient is considered a responder if improved in the MIDAS disability category (e.g., changed from grades 2-4 to lower category) at Month 3 from baseline. The responder rate refers to the proportion of patients with any improvement in the MIDAS disability category
*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. BL, baseline; CI, confidence interval; FAS, full analysis set; MIDAS, Migraine Disability Assessment; mMIDAS, modified MIDAS; OR, odds ratio; PBO, placebo; SE, standard error; TD, treatment difference; vs, versus

MPFID scores – Change at Month 3 from baseline

- At Month 3, there was a statistically significant improvement in the mean MPFID scores compared with placebo:
  - MPFID-PI: 140 mg: −4.27, difference: −1.96 [P=0.014], 70 mg: −3.95, difference: −1.64 [P=0.021], placebo: −2.31 (**Figure 3a**)
  - MPFID-EA: 140 mg: −5.61, difference: −2.42 [P=0.002], 70 mg: −4.94, difference: −1.75 [P=0.011], placebo: −3.19 (**Figure 3b**)

Figure 3a. Adjusted mean change from baseline in MPFID-PI by visit (FAS)

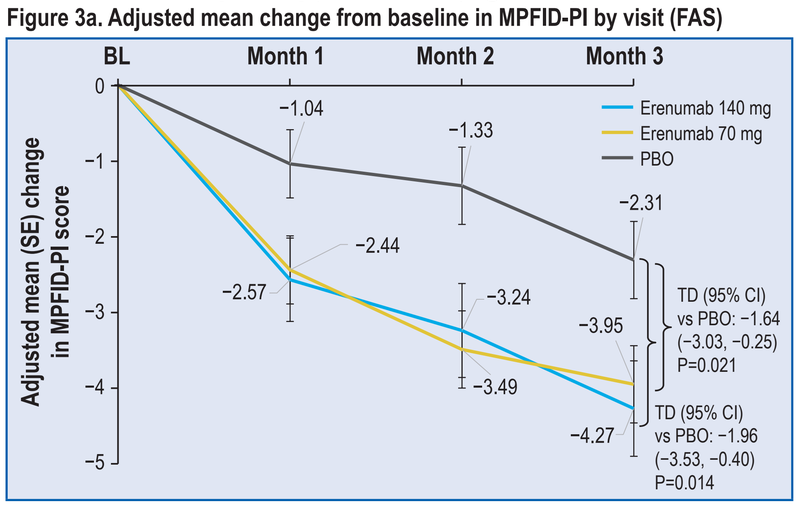
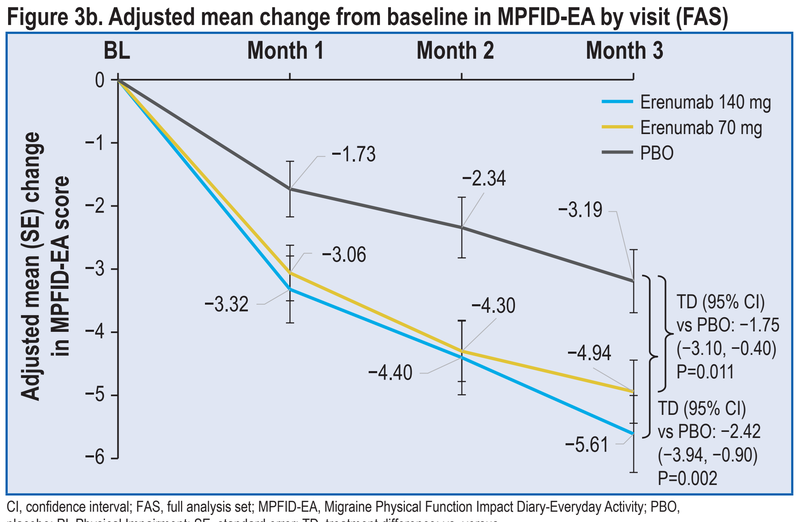


Figure 3b. Adjusted mean change from baseline in MPFID-EA by visit (FAS)

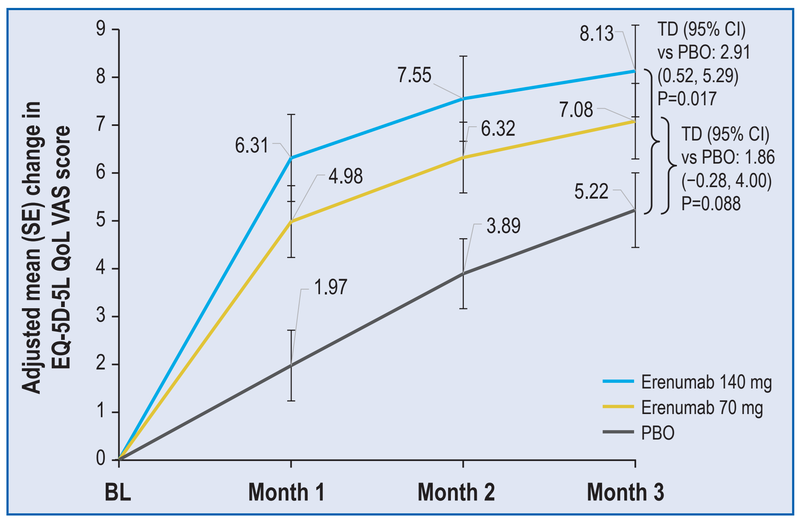


CI, confidence interval; FAS, full analysis set; MPFID-EA, Migraine Physical Function Impact Diary-Everyday Activity; PBO, placebo; PI, Physical Impairment; SE, standard error; TD, treatment difference; vs, versus

EQ-5D-5L – Change at Month 3 from baseline

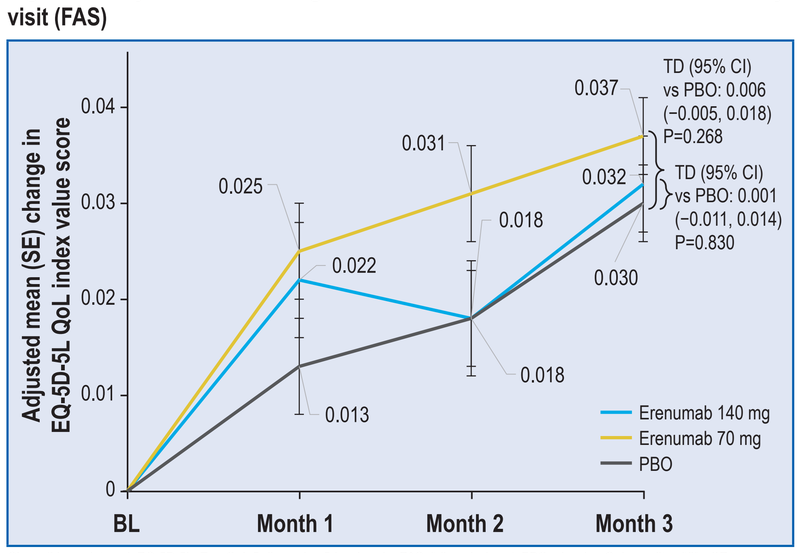
- A greater improvement in the mean EQ-5D-5L QoL visual analog scale (VAS) score with erenumab 140 mg (8.13, difference: 2.91, P=0.017) and 70 mg (7.08, difference: 1.86, P=0.088) compared with placebo (5.22) was noted (**Figure 4a**)

Figure 4a. Adjusted mean change from baseline in EQ-5D-5L QoL VAS score by visit (FAS)



- No meaningful differences in the change from baseline in mean EQ-5D-5L quality of life index values between erenumab groups and placebo were noted (**Figure 4b**)

Figure 4b. Adjusted mean change from baseline in EQ-5D-5L QoL index value by visit (FAS)



CI, confidence interval; EQ-5D-5L, EuroQoL 5-dimension 5-level scale; FAS, full analysis set; PBO, placebo; QoL, quality of life; SE, standard error; TD, treatment difference; VAS, visual analog scale; vs, versus

CONCLUSIONS

- In line with EM pivotal studies, this analysis of the EMPOwER study showed that both erenumab doses led to clinically meaningful improvements versus placebo in the migraine-related disability and various aspects of daily functioning in patients with EM in Asia, the Middle East and Latin America
- The PRO results reinforce the benefits of erenumab as an effective therapy for the prevention of migraine in patients with EM in Asia, the Middle East and Latin America

REFERENCES

1. Shi L, et al. *J Pharmacol Exp Ther*. 2016;356:223-31
2. Dodick D.W, et al. *Cephalalgia*, 2018;38:1026-37
3. Goadsby P.J, et al. *N Engl J Med*, 2017;377:2123-32
4. Goadsby P.J, et al. *Cephalalgia*, 2019;39:817-26
5. Tepper S, et al. *Lancet Neurol*, 2017;16:425-34
6. Ashina M, et al. *Cephalalgia*, 2018;38:1611-21
7. Wang SJ, et al. *Cephalalgia*, 2021;41(13):1285-97

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DISCLOSURES

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