Efficacy and Safety of Erenumab in Patients with Episodic Migraine in East Asia: Taiwan and Korea subpopulation analysis of the EMPOwER study

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Objective: EMPOwER (NCT03333109), a 3-month, double-blind, randomised study, evaluated the efficacy and safety of erenumab in adult patients with episodic migraine (EM) from Asia, the Middle East, and Latin America. The results from the subpopulation analysis of Taiwan and Korea are reported here.

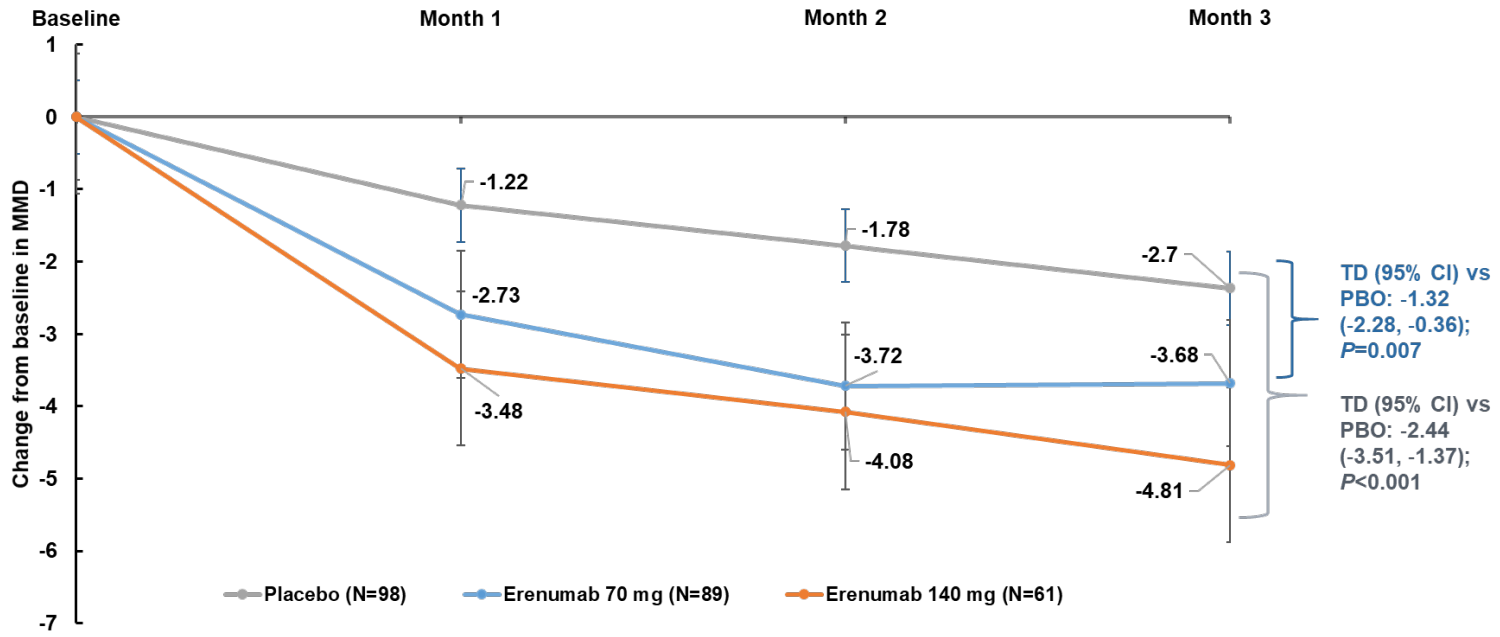
Methods: Overall, 249 randomised patients received placebo (PBO), erenumab 70mg or 140mg (3:3:2) for 3 months. The primary endpoint was change from baseline in monthly migraine days (MMD). Secondary endpoints assessed were achievement of ≥50% reduction in MMD, change in monthly acute migraine-specific medication treatment days (MSMD), Headache impact test (HIT-

6™) scores and safety. Assessments were done over the last month (Month 3) of the double-blind treatment period.

Results: At baseline, mean (standard deviation) age was 40.4 (10.3) years, 79.1% of patients were female and the mean MMD was 7.94 (2.39). At Month 3, a statistically significant reduction from baseline in mean MMD (**Figure**) was observed with erenumab compared with PBO; similarly, a higher proportion of patients achieved ≥50% reduction in MMD, and greater reductions in MSMD and HIT-6™ score were reported with erenumab versus PBO (**Table**). The safety profile of erenumab was in line with that of the global population with no newly-emergent safety signals.

Conclusions: The EMPOwER study confirms the efficacy and safety of erenumab 70mg and 140mg in adult patients with EM from Taiwan and Korea, consistent with results from the global population.

Figure: Change from baseline in MMD by treatment and visit (Full Analysis Set)



Error bars represent the standard error, *P*<0.05 was considered as statistically significant
CI, confidence interval; MMD, monthly migraine days; N, number of patients included in the analysis set; PBO, placebo; TD, treatment difference

N	Baseline	Month 1	Month 2	Month 3
Placebo	98	97	96	96
Erenumab 70 mg	89	89	89	89
Erenumab 140 mg	61	61	60	60

N, number of patients included in the analysis set

Table: Change from baseline in secondary endpoints at Month 3 (Full Analysis Set)

	Placebo	Erenumab 70 mg	Erenumab 140 mg
≥ 50% response rate			
m/M (%)	33/98 (33.7)	47/89 (52.8)	41/61 (67.2)
Odds ratio (95% CI)	-	2.14 (1.18, 3.85)	3.93 (2.00, 7.69)
p-value	-	0.011	<0.001
MSMD			
Mean change (SE)	–0.54 (0.25)	–1.50 (0.26)	−2.36 (0.31)
Mean difference (95% CI)	-	–0.95 (–1.64, –0.27)	–1.81 (–2.58, –1.05)
p-value	-	0.007	<0.001
HIT-6™			
Mean change (SE)	–4.77 (0.74)	–7.59 (0.79)	−7.98 (0.93)
Mean difference (95% CI)	-	–2.82 (–4.86, –0.78)	–3.21 (–5.49, –0.92)
p-value	-	0.007	0.006

A linear mixed effects model includes treatment group, baseline value, stratification factor, scheduled visit, and the interaction of treatment group with scheduled visit. Unstructured covariance matrix assumed.

CI, confidence interval; HIT-6, headache impact test score; M, the total number of patients in the treatment group with response variable defined; m, the number of patients who responded; MSMD, monthly acute migraine-specific medication treatment days; N, number of patients included in the analysis set; n: number of patients with non-missing value at the corresponding time point of interest; SE, standard error

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Disclosure of Interest:

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