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

Shuu-Jiun Wang[1], Byung Kun Kim[2], Gabriel Paiva da Silva Lima[3], Shaloo Pandhi[4], Shihua Wen[5], Subhayan Mondal[6], Peggy Hours-Zeisger[4]

[1]Neurological Institute, Taipei Veterans General Hospital, Taipei, Taiwan; [2]Eulji University School of Medicine; [3]Amgen, Inc., Thousand Oaks, CA, USA; [4]Novartis PharmaAG, Basel, Switzerland; [5]Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA; [6]Novartis Healthcare Pvt. Ltd., Hyderabad, Indian

One Sentence Summary: The East Asian subpopulation analysis of the EMPOwER study presents efficacy and safety of erenumab (70 and 140 mg) in adult patients with episodic migraine (EM) from Taiwan and Korea.

Background: Erenumab (erenumab-aooe in the United States) is a fully human monoclonal antibody targeting the canonical calcitonin gene-related peptide receptor. Erenumab has demonstrated efficacy and safety in EM and chronic migraine in various studies[1-4]. The majority of studies were conducted in North America and Europe and there remains an unmet need for appropriate management of migraine in Asia; this represents nearly a third of the world's population. The EMPOwER study has demonstrated the efficacy and safety of erenumab in Asia, the Middle East, and Latin America. The efficacy and safety of erenumab (70 and 140 mg) are explored here in adult patients with EM from the East Asian subpopulation (Taiwan and Korea).

Methods: EMPOwER (NCT03333109), a 3-month, double-blind, randomized, placebo-controlled, Phase 3 study, evaluated the efficacy and

safety of erenumab in adult patients with EM from Asia, the Middle East, and Latin America. The results from the subpopulation analysis of Taiwan and Korea are reported. Overall, 249 randomized patients received placebo (PBO), erenumab 70 mg or 140 mg (3:3:2) for 3 months. The primary endpoint was the change from baseline in monthly migraine days (MMD). Secondary endpoints assessed included the achievement of 50% reduction in MMD, change in monthly acute migraine-specific medication treatment days (MSMD), changes in headache impact test (HIT-6™), and assessment of safety. Assessments were done over the last month (Month 3) of the double-blind treatment period.

Results: At baseline, the mean (standard deviation) age was 40.4 (±10.3) years; 79.1% patients were female and the mean MMD was 7.94 (2.39). At Month 3 there was a statistically significant greater reduction from baseline in mean MMD for erenumab 70 mg (-3.68 days, P=0.007 vs PBO) and 140 mg (-4.81 days, P=0.001 vs PBO) compared with PBO (- 2.37 days [Figure]). A higher proportion of patients achieved 50% reduction in MMD with erenumab 70 mg (52.8%, P=0.011 vs PBO) and 140 mg (67.2%, P< 0.001 vs PBO) compared with PBO (33.7% [Table]). There was a greater reduction in MSMD with erenumab 70 mg (-1.5, P=0.007 vs PBO) and 140 mg (- 2.36, P< 0.001 vs PBO) compared with PBO (-0.54). Similarly, a greater reduction in the HIT-6™ score with erenumab 70 mg (-7.59, P=0.007 vs PBO}, and 140 mg (-7.98, P=0.006 vs PBO) compared with PBO (- 4.77) was reported. In general, the safety profile of erenumab was in line with that of the global population; there were no newly-emergent safety signals.

Conclusion: The EMPOwER study showed the efficacy and safety of erenumab (70 and 140 mg) in adult patients with EM from Taiwan and Korea, consistent with the results from the global population. A consistent numerical benefit was observed with erenumab (140 mg and 70 mg) versus placebo across all efficacy endpoints.

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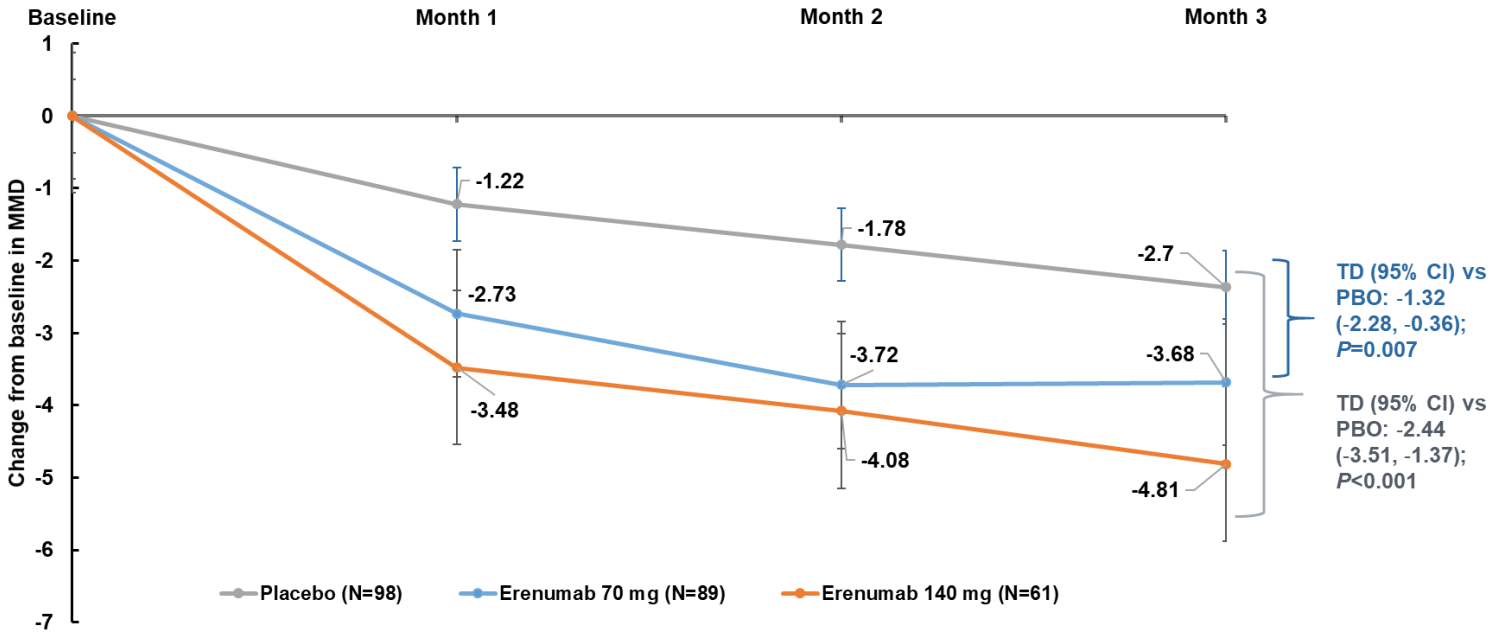
Figure: Change from baseline in MMD by treatment and visit (Full Analysis Set)



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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