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Reversion From Chronic to Episodic Migraine and Effects on Patient-reported Outcomes Following Treatment With Erenumab: Post-hoc Analysis of the Randomised, 12-week, Double-blind DRAGON Study

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Introduction: The efficacy and safety of erenumab were confirmed in patients with chronic migraine (CM) from Asia in the 12-week, double-blind treatment phase (DBTP) of the randomised, placebo-controlled, Phase 3 DRAGON study (NCT03867201).
Objectives: This post-hoc analysis evaluated the efficacy of erenumab in patients with CM by assessing the reversion rate from CM to episodic migraine (EM) in the overall population and in the subgroups defined by baseline clinical and demographic characteristics, and effects on patient-reported outcomes (PROs) over the 12 weeks of treatment.
Methods: Adult patients with CM (N=557) (defined as ≥15 headache days per month, of which ≥8 were migraine days, in each of prior 3 months) were randomised (1:1) to monthly subcutaneous erenumab 70 mg (n=279) or placebo (n=278). Reversion to EM was defined as patients with <45 headache days over the 12-week DBTP. PROs including Headache Impact Test-6 (HIT-6), Migraine Physical Function Impact Diary (MPFID), and modified Migraine Disability Assessment (mMIDAS) were also evaluated. The change in MIDAS disability category was assessed, with converted mMIDAS scores calculated as a sum of all 3-monthly assessments.

Table:

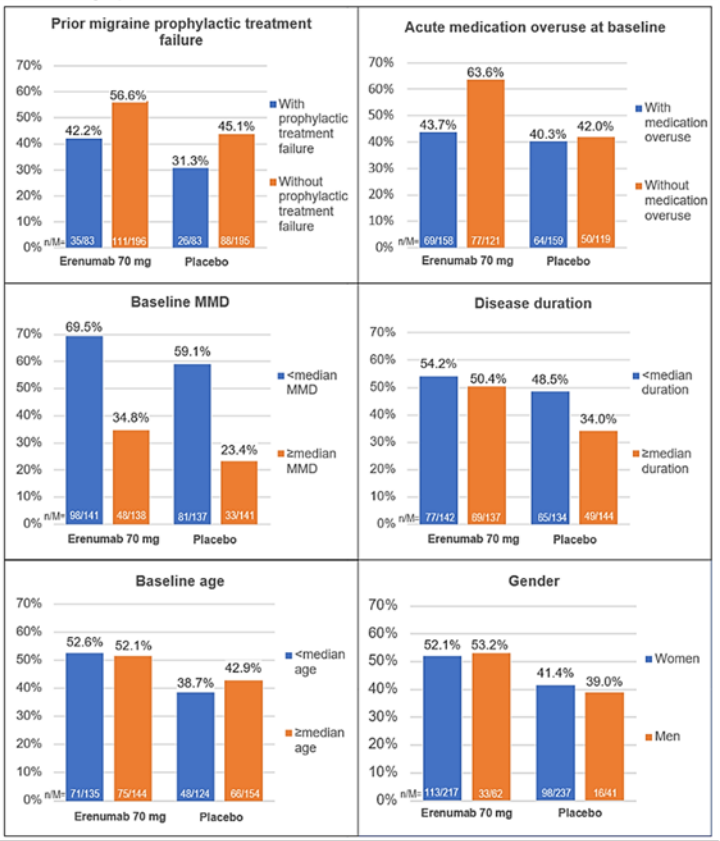
Change from baseline in PROs (full analysis set)								
	Erenumab 70 mg				Placebo			
Change from baseline	Reversing to EM		Not reversing to EM		Reversing to EM		Not reversing to EM	
	n	Mean (SE)	n	Mean (SE)	n	Mean (SE)	n	Mean (SE)
HIT-6	140	−9.5 (0.65)	123	−5.1 (0.58)	114	−8.9 (0.72)	154	−4.9 (0.52)

MPFID-PI	146	−5.9 (0.36)	124	−1.9 (0.61)	114	−5.4 (0.41)	160	−1.0 (0.54)
MPFID-EA	146	−7.9 (0.48)	124	−3.4 (0.65)	114	−7.1 (0.55)	160	−3.2 (0.58)
mMIDAS	140	−22.1 (1.24)	123	−6.3 (1.81)	114	−19.9 (1.38)	154	−7.9 (1.62)
Status at Week 12	**n**	**M (%)**	**n**	**M (%)**	**n**	**M (%)**	**n**	**M (%)**
Improved in MIDAS disability category	46	146 (31.5)	33	133 (24.8)	31	114 (27.2)	19	164 (11.6)

EA, everyday activities; EM, episodic migraine; HIT-6, Headache Impact Test-6; M, number of patients included in the analysis set (percentage uses M as denominator); mMIDAS, modified Migraine Disability Assessment; MPFID, Migraine Physical Function Impact Diary; n, number of patients with non-missing value at the corresponding time point of interest; PI, physical impairment; PRO, patient-reported outcome; SE, standard error. Since mMIDAS scoring is based on a 1-month recall period, the original MIDAS disability categories were based on converted mMIDAS scores, calculated as a sum of all 3-monthly assessments, representing 3-months recall period. Change to lower disability category after baseline is considered an improvement. MPFID presented as change from baseline in monthly days with physical impairment (PI) or impact on everyday activities (EA) at Week 12 (response of 3, 4, or 5 on any of the 5 daily items). Patients with missing data are counted in the not reverting to EM subpopulation. For patients who continued to the open-label treatment phase, the cutoff is end-of-treatment. For patients who entered safety follow-up after the double-blind treatment phase, the cutoff is 11-Aug-2021 or end of study, whichever is the earliest.

Image:

Figure. Proportion of patients reversing from CM to EM at Week 12 by baseline clinical and demographic characteristics



CM, chronic migraine; EM, episodic migraine; M, total number of patients within the subgroup level in the treatment group; MMD, monthly migraine day; n, number of patients who responded
The value of the stratification factor (prior prophylactic migraine treatment failure & medication overuse) used here is the one used for randomisation.
For patients who continued to open-label treatment, the cutoff is end-of-treatment. For patients who entered safety follow-up after double-blind treatment, the cutoff is 11-Aug-2021 or end of study, whichever is the earliest

Results: In total, 545 patients (97.8%) completed the DBTP. Overall, a greater proportion of patients on erenumab reverted to EM after 12 weeks of treatment than on placebo (52.3% vs 41.0%, OR 1.59, 95% CI: 1.13, 2.23; p=0.007), which was consistent across all subgroups (prior preventive treatment failure, medication overuse, disease duration, baseline monthly migraine days, age, and gender) (**Figure**). Moreover, additional benefit was reflected with a greater improvement in analysed PROs in patients who reverted from CM to EM: reductions in HIT-6™ and mMIDAS scores, improvements in monthly days with physical impairment and everyday activities in MPFID, and proportion of patients improving in MIDAS disability category (**Table**).

Conclusion: Results from this post-hoc analysis demonstrated that patients treated with erenumab 70 mg have a higher chance of reverting from CM to EM compared to placebo, which is consistent through clinically heterogenous groups of CM patients in Asia. Reversion to EM is associated with improvement in migraine-related disability and quality of life as measured by PROs.

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