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Erenumab in episodic and chronic migraine: Post-hoc analysis of efficacy data by high- versus low-frequency migraine in Phase 2 and Phase 3 studies

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Uwe Reuter[1*], David W Dodick[2], Stewart J Tepper[3], Shannon Ritter[4], Gabriel Paiva da Silva Lima[5], Denise E Chou[5], Ronald Zielman[6], Messoud Ashina[7]

[1]Department of Neurology, Charité Universitätsmedizin Berlin, Berlin, Germany; [2]Department of Neurology, Mayo Clinic, Scottsdale, AZ, USA; [3]Geisel School of Medicine at Dartmouth, Hanover, NH, USA; [4]Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA; [5]Amgen Inc., Thousand Oaks, CA, USA; [6]Novartis Pharma B.V., Amsterdam, Netherlands; [7]Department of Neurology, Danish Headache Center, Rigshospitalet Glostrup, Faculty of Health and Medical Sciences, University of Copenhagen, Copenhagen, Denmark

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Background, Methods and Results

Background

- The distinction between episodic and chronic migraine is based on the number of migraine and headache days in a month.[1] However, migraine frequency varies within patients over time and the classification of EM versus CM is not necessarily representative of migraine-related disability or severity (e.g. patients with HFEM may have a similar disease burden as patients with CM[2])
- Here, we present efficacy data for erenumab (70 mg and 140 mg) from the low- and high-frequency EM and CM subgroups in a post-hoc analysis of two pivotal studies: a Phase 3 study in EM patients (STRIVE, NCT02456740)[3] and a Phase 2 study in CM patients (NCT02066415)[4]

Methods

- The two studies included in the post-hoc analysis had a similar placebo-controlled study design and compared the two doses of erenumab (70 mg and 140 mg) versus placebo, but differed in the double-blind treatment phase duration and sample size
- In this post-hoc analysis, subgroups were defined by baseline MMD within EM and CM subgroups and included LFEM (4–7 MMD), HFEM (8–14 MMD), LFCM (8–14 MMD) and HFCM (≥15 MMD)
- Outcomes assessed included the change from baseline in MMD and the proportion of patients who achieved ≥50% reduction from baseline in MMD
- Outcomes were assessed over Months 4–6 for the EM study and at Month 3 for the CM study

Results

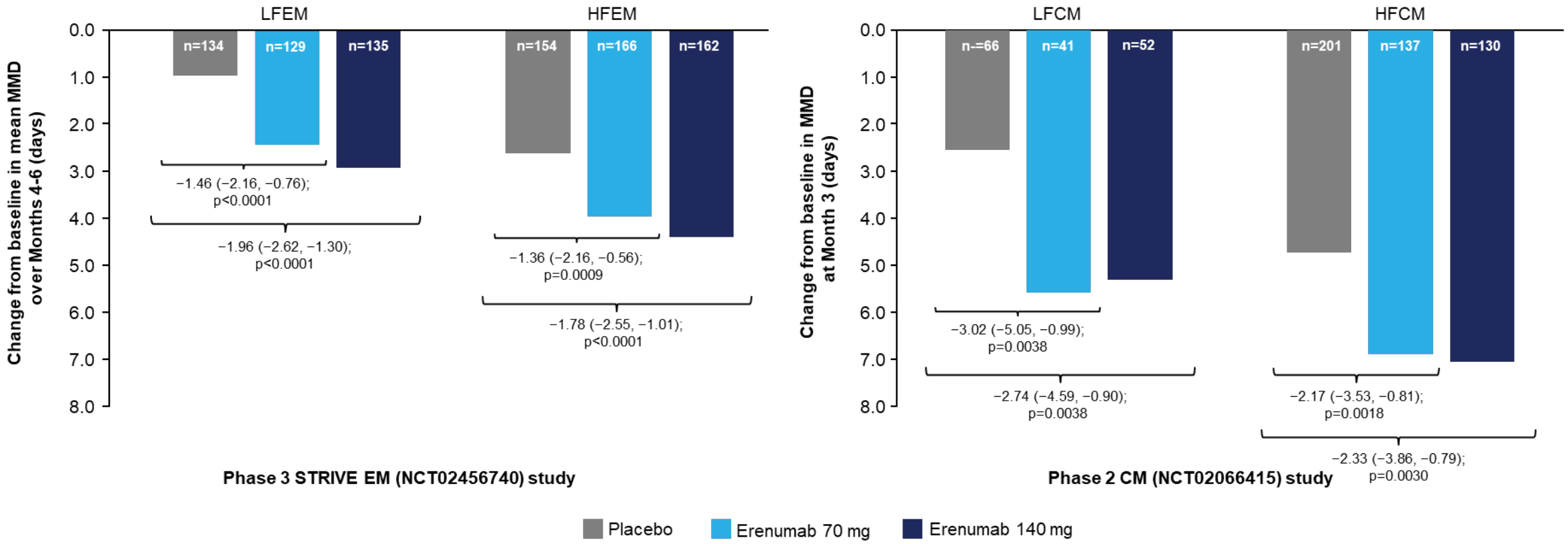
- The mean MMD (SD) at baseline in the placebo and erenumab (70 mg and 140 mg) groups, respectively, were:
  - LFEM subgroup: 6.10 (1.03), 6.12 (1.03) and 6.28 (1.0); HFEM subgroup: 10.19 (1.70), 10.07 (1.69) and 10.04 (1.75)
  - LFCM subgroup: 12.35 (1.82),12.63 (1.57) and 12.47 (1.95); HFCM subgroup: 20.26 (3.49), 19.56 (3.57) and 19.94 (3.61)

CM, chronic migraine; EM, episodic migraine; HFCM, high-frequency chronic migraine; HFEM, high-frequency episodic migraine; LFCM, low-frequency chronic migraine; LFEM, low-frequency episodic migraine; MHD, monthly headache days; MMD, monthly migraine days; SD, standard deviation.

[1]Headache Classification Committee of the International Headache Society. Cephalalgia. 2018;38(1):1–211. [2]Torres-Ferrus M, et al. Cephalalgia. 2017;37(2):104–113. [3]Goadsby PJ, et al. N Engl J Med. 2017;377(22):2123–2132. [4]Tepper S, et al. Lancet Neurol. 2017;16(6):425–434.

Results

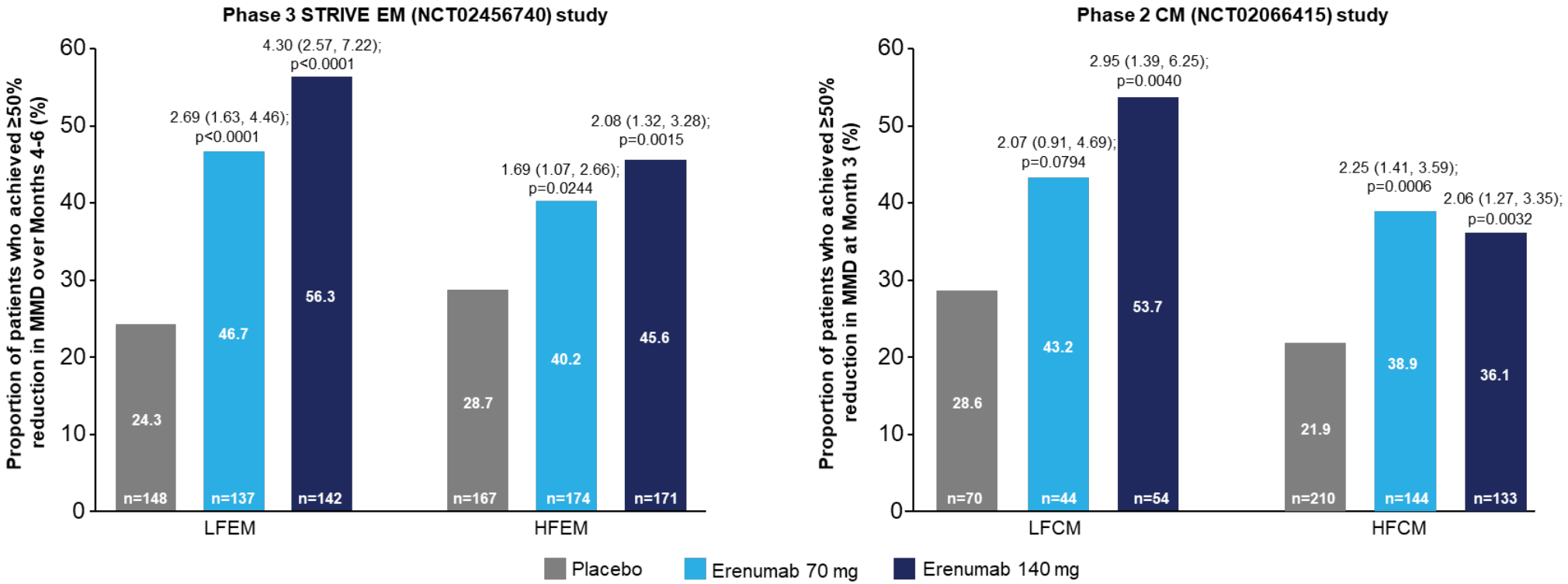
- Erenumab at both doses (70 mg and 140 mg) significantly reduced MMD across all of the subgroups (LFEM, HFEM, LFCM and HFCM) compared with placebo in the double-blind treatment phase of both studies



Data are presented as treatment difference of least square mean (95% confidence interval) and p-value relative to placebo. p-values are nominal, without multiplicity adjustment and indicate statistical significance (two-sided) at a level of 0.05. HFCM, high-frequency chronic migraine; HFEM, high-frequency episodic migraine; LFCM, low-frequency chronic migraine; LFEM, low-frequency episodic migraine; MMD, monthly migraine days; n, the number of patients assessed in each treatment group.

Results and Conclusion

- The proportion of patients achieving ≥50% reduction from baseline in MMD was significantly higher with erenumab when compared with placebo in all of the subgroups except for the LFCM subgroup, in which the difference between erenumab 70 mg and placebo did not reach nominal significance potentially due to small sample sizes



Data are presented as odds ratio (95% confidence interval) and p-value relative to placebo. p-values are nominal, without multiplicity adjustment and indicate statistical significance (two-sided) at a level of 0.05. The statistical analysis utilises a Cochran-Mantel-Haenszel test adjusting for the stratification factor. Patients with missing assessment were considered non-responders. HFCM, high-frequency chronic migraine; HFEM, high-frequency episodic migraine; LFCM, low-frequency chronic migraine; LFEM, low-frequency episodic migraine; MMD, monthly migraine days; n, the sample size that was used for calculation of percentage in each treatment group.

Conclusion

- This post-hoc analysis supports the efficacy of erenumab across the entire migraine spectrum, including in the clinically relevant subgroup of high-frequency EM which may have a similar disease burden as CM