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Reversion From Chronic to Episodic Migraine in Patients With Documented Inadequate Response to 2-4 Classes of Migraine Preventive Treatments: Results of the Randomized, Placebo-controlled FOCUS Study

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CONCLUSIONS

- **Higher proportions of patients with chronic migraine (CM) reverted to episodic migraine (EM) with fremanezumab treatment than with placebo in this population of patients with inadequate response to 2 to 4 classes of migraine preventive treatments**
- **On average, higher proportions of patients in the fremanezumab groups who reverted from CM to EM experienced ≥50% clinically meaningful reductions in monthly average number of headache days during the 3-month double-blind treatment period, with similar reductions in headache days of at least moderate severity observed at all 3 monthly time points**
- **These results indicate that patients with migraine can revert to a less severe form of the disease with fremanezumab treatment, along with experiencing clinically meaningful reductions in headache days**

INTRODUCTION

- CM is a common and disabling neurologic disease; however, regular use of preventive treatments has been shown to reduce the frequency of migraine, allowing for reversion from CM to EM, which is associated with a lower disease burden[1]
- Fremanezumab, a fully humanized monoclonal antibody (IgG2Δa) that selectively targets calcitonin gene-related peptide (CGRP),[2] has proven efficacy for preventive treatment of migraine in adults[3,4]
- The FOCUS study (ClinicalTrials.gov Identifier: NCT03308968) of fremanezumab was the first and largest study of a migraine preventive treatment in a population of adults with difficult-to-treat migraine and documented inadequate response to 2 to 4 classes of migraine preventive medications

OBJECTIVE

- To evaluate the proportion of patients reverting from CM at baseline to EM in all 3 months of study treatment, along with reductions in the monthly average number of headache days among patients who reverted

METHODS

Patients

- The FOCUS study included adult patients with EM or CM who had a documented inadequate response to 2 to 4 classes of prior migraine preventive medications
- This subgroup analysis included patients who reverted from CM at baseline to EM (**Box 1**)

Box 1. Subgroup Analysis Population

Patients Who Reverted From CM to EM

CM → **EM**

≥15 headache days per month at baseline

<15 headache days per month in Months 1, 2, 3

CM, chronic migraine; EM, episodic migraine.

Study Design

- International, multicenter, randomized, double-blind, placebo-controlled, phase 3 study
- Included a screening visit; 28-day run-in period; 12-week, double-blind, placebo-controlled treatment period; and 12-week, open-label treatment period
- During the double-blind period, patients were randomized (1:1:1) to subcutaneous (SC) quarterly fremanezumab (Months 1, 2, 3: 675 mg, placebo, placebo), SC monthly fremanezumab (Months 1, 2, 3: 225 mg [EM]/675 mg [CM], 225 mg, 225 mg), or matched monthly placebo

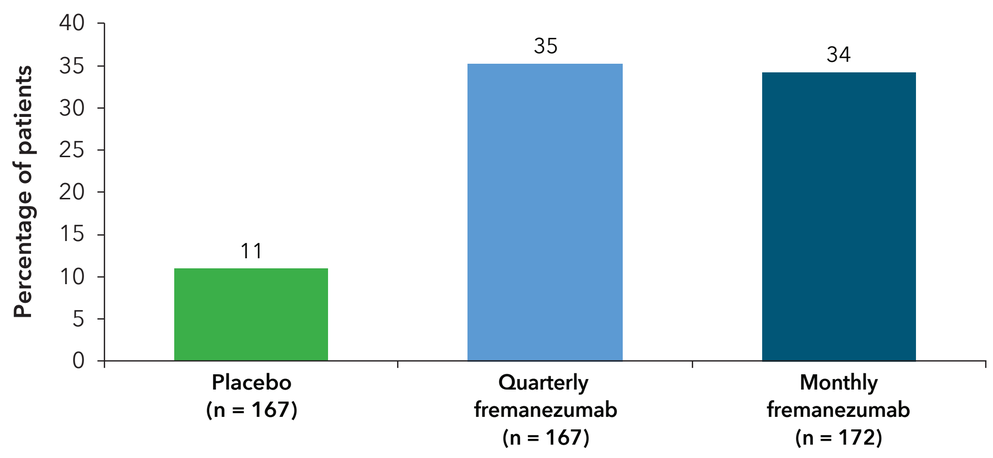
Study Assessments

- Overall headache days for patients who reverted from CM at baseline to EM at Months 1, 2, and 3 were evaluated at baseline and Month 3, along with percent change in overall headache days from baseline to Month 3
- Monthly average number of headache days of at least moderate severity in all 3 months was also evaluated in this population

RESULTS

Patients

Figure 1. Proportion of patients who reverted from CM to EM in Months 1, 2, and 3.

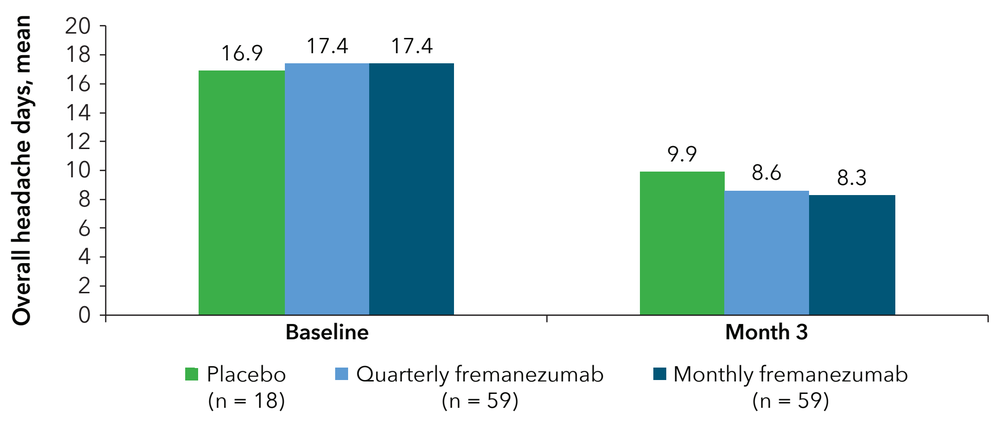


CM, chronic migraine; EM, episodic migraine.

- The proportions of patients reverting from CM to EM are summarized in **Figure 1**

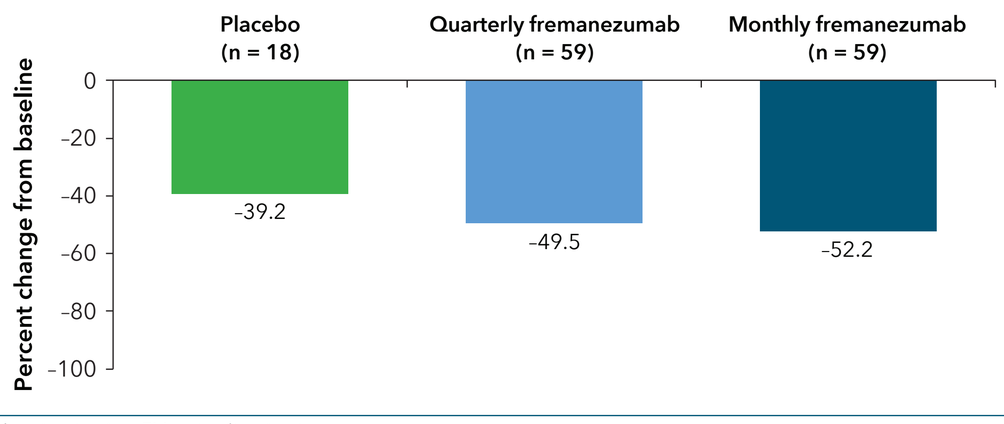
Efficacy in Patients Who Reverted From CM to EM

Figure 2. In patients who reverted from CM to EM, mean overall headache days at baseline and Month 3.



CM, chronic migraine; EM, episodic migraine.

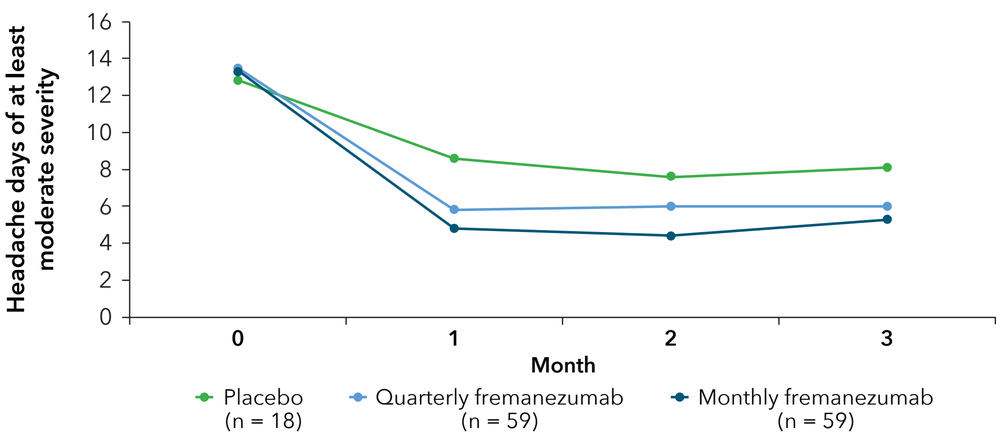
Figure 3. In patients who reverted from CM to EM, percent change from baseline in overall headache days at Month 3.



CM, chronic migraine; EM, episodic migraine.

- Among patients who reverted from CM to EM, patients in the quarterly and monthly fremanezumab groups experienced a lower number of overall headache days (**Figure 2**) and a greater percent decrease in mean overall headache days from baseline (**Figure 3**) at Month 3 than those in the placebo group

Figure 4. In patients who reverted from CM to EM, monthly average number of headache days of at least moderate severity at Months 1, 2, and 3.



CM, chronic migraine; EM, episodic migraine.

- Among patients who reverted from CM to EM, reductions from baseline in headache days of at least moderate severity were also greater with quarterly or monthly fremanezumab versus placebo at Months 1, 2, and 3 (**Figure 4**)

References

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Disclosures

J. Ailani reports the following conflicts of interest: consulting for Amgen, Alder, Allergan, Alpha Sites Consulting, Biohaven, electroCore, Eli Lilly and Company, Promius, Impel, Satsuma, Supernus, and Teva Pharmaceuticals; speakers bureau for Allergan, Amgen, Eli Lilly and Company, electroCore, Promius, and Teva Pharmaceuticals; content development/delivery (CME/non-CME) for Aptus, PeerView, Medscape, Miller Medical, Medical Education International, and Neurology Live; clinical trials: American Registry for Migraine Research (American Migraine Foundation); and section editor for *Current Pain and Headache Reports*. V. Ramirez-Campos, J.M. Cohen, R. Yang, M. Galic, and X. Ning are employees of Teva Pharmaceuticals. R. Halker Singh has received honoraria from Biohaven and Amgen for serving on advisory boards.

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