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Efficacy of Fremanezumab in Male Patients With Migraine and Documented Inadequate Response to 2-4 Classes of Migraine Preventive Treatments: Results of the Randomized, Placebo-controlled FOCUS Study

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CONCLUSIONS

- **This subgroup analysis demonstrated statistically significant improvements in efficacy outcomes due to the strong effect size versus placebo in male migraine patients**
- **Reductions in the monthly number of migraine and headache days of at least moderate severity were significantly greater with fremanezumab versus placebo in male patients**
- **These results may be particularly meaningful for health care providers treating male patients, for whom the impact of migraine is often underestimated and undertreated**

INTRODUCTION

of men experience migraine[1]

Strong efficacy results for migraine preventive treatments in men are lacking

- 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 efficacy of fremanezumab in a subgroup, which included only male migraine patients from this study, over 12 weeks of double-blind treatment

METHODS

Patients

- This study included adult patients with episodic migraine (EM) or chronic migraine (CM) with documented inadequate response to 2 to 4 classes of prior migraine preventive medications
- This subgroup analysis included only the male patients from this study

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

- For male patients, changes from baseline in the monthly average number of migraine days and the monthly average number of headache days of at least moderate severity over 12 weeks of double-blind treatment were evaluated
- Proportions of male patients achieving a ≥50% reduction in the monthly average number of migraine days over 12 weeks of double-blind treatment were also evaluated

RESULTS

Patients

Table 1. Male Subgroup: Baseline Monthly Average Migraine Days and Headache Days of at Least Moderate Severity

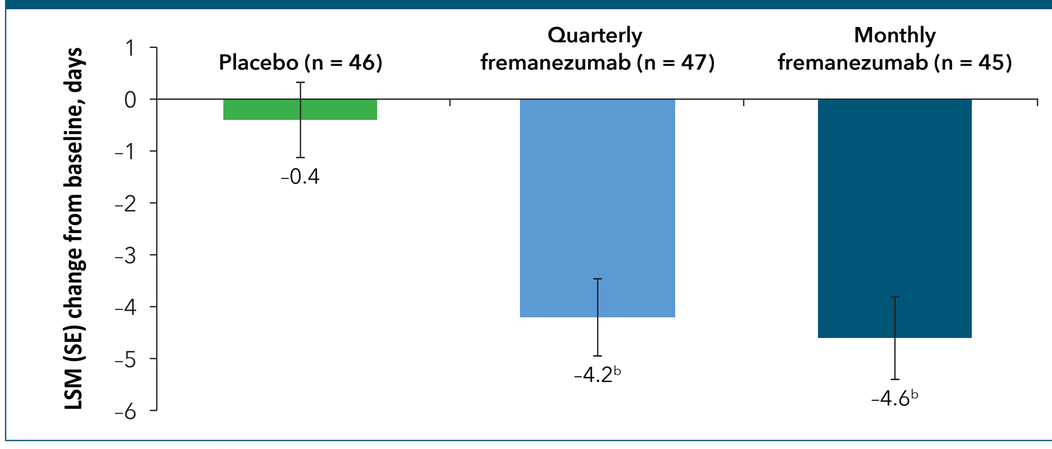
Baseline values, mean (SD)	Placebo (n = 46)	Quarterly fremanezumab (n = 47)	Monthly fremanezumab (n = 45)
Monthly average migraine days	13.8 (6.5)	15.1 (5.9)	15.9 (5.1)
Monthly average headache days of at least moderate severity	12.9 (6.7)	13.0 (6.3)	14.3 (5.5)

SD, standard deviation.

- In the male subgroup population (n = 138), baseline monthly average numbers of migraine days and headache days of at least moderate severity are summarized in **Table 1**

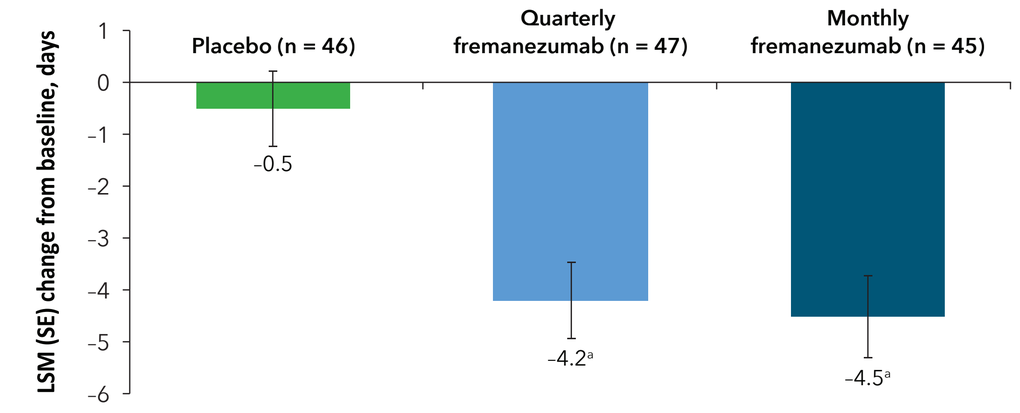
Efficacy in Male Migraine Patients

Figure 1. In male patients, change from baseline in the monthly average number of migraine days over 12 weeks of treatment.[a]



LSM, least-squares mean; SE, standard error.
[a]Results for female patients: placebo (n = 232), –0.6; quarterly fremanezumab (n = 229), –3.6; monthly fremanezumab (n = 238), –3.9; *P* <0.0001 for both comparisons.
[b]*P* <0.0001 versus placebo.

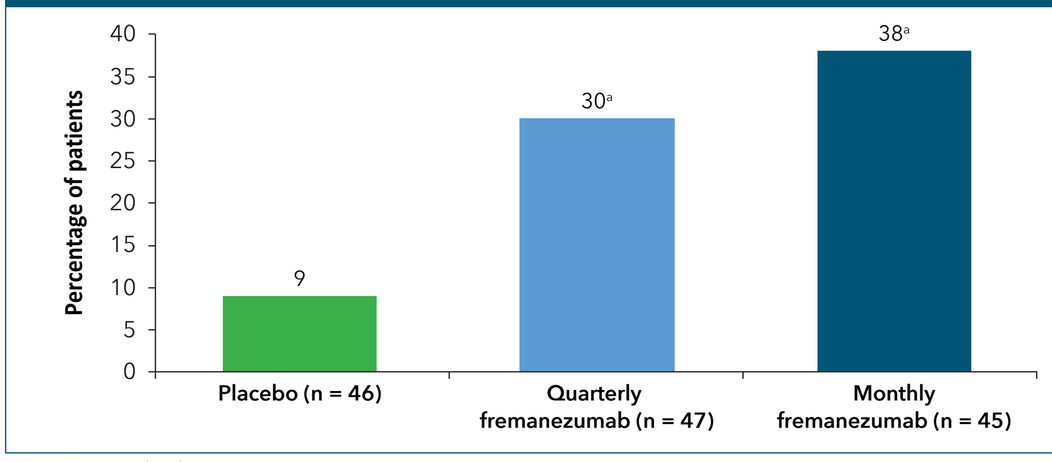
Figure 2. In male patients, change from baseline in the monthly average number of headache days of at least moderate severity over 12 weeks of treatment.



LSM, least-squares mean; SE, standard error.
[a]*P* <0.0001 versus placebo.

- In male patients, reductions from baseline in the monthly average number of migraine days (**Figure 1**) and monthly average number of headache days of at least moderate severity (**Figure 2**) over 12 weeks were significantly greater with fremanezumab versus placebo

Figure 3. Proportion of male patients achieving ≥50% reduction in the monthly average number of migraine days over 12 weeks of fremanezumab treatment.



[a]*P* <0.05 versus placebo.

- Proportions of male patients achieving ≥50% reduction in the monthly average number of migraine days from baseline over 12 weeks were also significantly greater with fremanezumab versus placebo (**Figure 3**)

References

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