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Effect of Fremanezumab on Quality of Life and Health Status in Migraine Patients With Documented Inadequate Response to 2-4 Classes of Migraine Preventive Medications in the Randomized, Placebo-controlled FOCUS Study

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CONCLUSIONS

- **Quarterly and monthly fremanezumab significantly improved migraine-specific quality of life (MSQoL) compared with placebo in patients with episodic migraine (EM) and chronic migraine (CM) and documented inadequate response to 2 to 4 classes of prior migraine preventive medications**
- **Both fremanezumab dosing regimens also significantly improved overall health status per the 5-level EuroQol-5 Dimension (EQ-5D-5L) questionnaire versus placebo**
- **These results support the strong clinical benefits observed with fremanezumab in this population of patients with difficult-to-treat EM and CM**

INTRODUCTION

- Migraine is associated with a substantial negative impact on health-related quality of life (HRQoL)[1,2]
- Fremanezumab is a fully humanized monoclonal antibody (IgG2Δa) that selectively targets calcitonin gene-related peptide (CGRP)
  - Approved for the preventive treatment of migraine in adults[3]
- The FOCUS study of fremanezumab was the first and largest study of a migraine preventive treatment in patients with EM and CM who had documented inadequate response to 2 to 4 classes of migraine preventive medications

OBJECTIVE

- To evaluate the effect of subcutaneous (SC) quarterly or monthly fremanezumab on MSQoL and health status in patients with EM or CM and documented inadequate response to 2 to 4 classes of migraine preventive medications

METHODS

Patients

Table 1. Key Selection Criteria

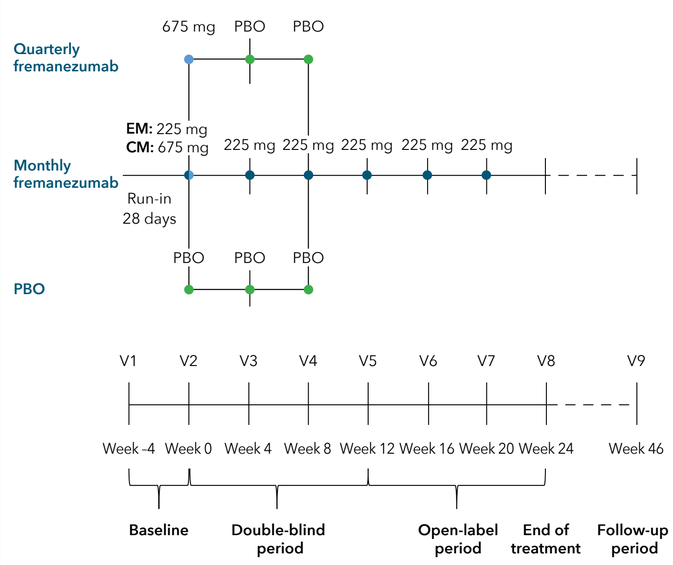
Inclusion criteria	Exclusion criteria
— Adult patients (18-70 years of age) with a diagnosis of migraine, with onset at ≤50 years — History of migraine for ≥12 months prior to screening and fulfilled criteria for EM or CM at baseline — Documented inadequate response (within the past 10 years) to 2-4 classes of prior migraine preventive medications: – Beta-blocker (propranolol, metoprolol, atenolol, bisoprolol) – Anticonvulsant (topiramate) – Tricyclic antidepressant (amitriptyline) – Calcium channel blocker (flunarizine) – OnabotulinumtoxinA – Valproic acid	— Any migraine preventive treatment use for >5 days at screening and plan to continue treatment — OnabotulinumtoxinA during the 3 months prior to screening — Opioid- or barbiturate-containing treatment on >4 days during the run-in period — Intervention/device for migraine during the 2 months prior to screening — Triptans, ergots, or nonsteroidal anti-inflammatory drugs for migraine preventive treatment — Prior exposure to a mAb targeting the CGRP pathway

EM, episodic migraine; CM, chronic migraine; mAb, monoclonal antibody; CGRP, calcitonin gene-related peptide.

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 (**Figure 1**)
  - Results of the 12-week, double-blind period are presented here
- During the double-blind period, patients were randomized (1:1:1) to SC quarterly fremanezumab, SC monthly fremanezumab, or placebo (**Figure 1**)

Figure 1. Study design and dosing for EM and CM patients.



EM, episodic migraine; CM, chronic migraine; PBO, placebo; V, visit.

Study Assessments

- The following exploratory efficacy outcomes were evaluated:
  - Change from baseline at 4 weeks after administration of the third dose of study drug in the 3 MSQoL questionnaire domain scores (scored 0-100; higher scores indicated better quality of life)
    - Role function – restrictive
    - Role function – preventive
    - Emotional function
  - Mean change from baseline at 4 weeks after administration of the third dose of study drug in the EQ-5D-5L questionnaire visual analog scale score (100-mm scale; 0 = worst imaginable health state; 100 = best imaginable health state)

RESULTS

Patients

- Efficacy analysis population, N = 837 (placebo, n = 278; quarterly fremanezumab, n = 276; monthly fremanezumab, n = 283)
- Demographics and baseline characteristics were well balanced across treatment groups
  - The mean (standard deviation [SD]) age was 46.2 (11.0) years, and the majority of patients (84% [700/838]) were female
  - The mean (SD) time since migraine diagnosis was 24.2 (13.4) years
  - 329 (39%) patients had EM, and 509 (61%) patients had CM

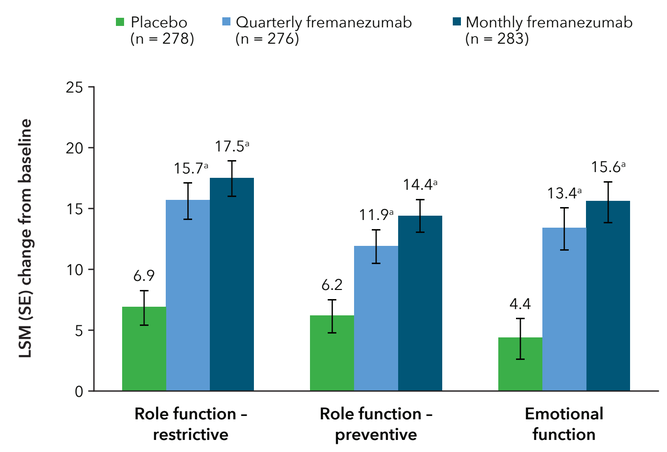
HRQoL

- Improvements from baseline in all MSQoL domain scores were significantly greater with quarterly and monthly fremanezumab versus placebo at 4 weeks after the third dose of study drug (all P <0.0001; **Figure 2**)

Health Status

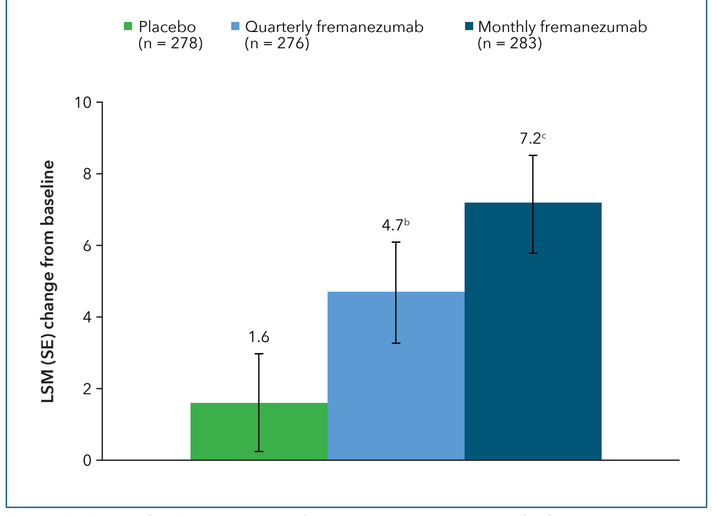
- Improvements from baseline in the EQ-5D-5L visual analog scale were significantly greater with quarterly and monthly fremanezumab versus placebo (both P <0.05; **Figure 3**)

Figure 2. Change from baseline in MSQoL domain scores at 4 weeks after the third dose of study drug.



MSQoL, migraine-specific quality of life; LSM, least-squares mean; SE, standard error.
[a]P <0.0001 versus placebo.

Figure 3. Change from baseline in the EQ-5D-5L visual analog scale[a] during the 4 weeks after the third dose of study drug.



EQ-5D-5L, EuroQol-5 Dimension; LSM, least-squares mean; SE, standard error.
[a]100-mm scale.
[b]P = 0.0426 versus placebo.
[c]P = 0.0002 versus placebo.

References

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Disclosures

L. Mechtler served as an investigator on this study for Teva Pharmaceuticals. P. Pozo-Rosich has received honoraria as a consultant and speaker for Allergan, Almirall, Chiesi, Eli Lilly, Novartis, and Teva Pharmaceuticals; and her research group has received research grants from Allergan and has received funding for clinical trials from Alder, electroCore, Eli Lilly, Novartis, and Teva Pharmaceuticals. P. Pozo-Rosich does not own stocks from any pharmaceutical company. X. Ning, M. Galic, J.M. Cohen, and R. Yang are employees of Teva Pharmaceuticals.

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