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Functioning and Work Performance After Long-term Treatment With Fremanezumab in Migraine Patients: A Patient Survey Study Following Completion of a 1-year Extension Study

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Dawn C. Buse,[1] Blaine Cloud,[2] Sanjay K. Gandhi,[3] Joshua M. Cohen,[3] Verena Ramirez-Campos,[3] Richard B. Lipton[1]

[1]Department of Neurology, Albert Einstein College of Medicine, New York, NY, USA; [2]Clinical SCORE, Chadds Ford, PA, USA; [3]Teva Pharmaceuticals Industries, Frazer, PA, USA.

CONCLUSIONS

- **Approximately three-quarters of patients surveyed reported that longer-term treatment with monthly or quarterly fremanezumab was associated with improvements in social interactions (quality and amount of time spent with family/friends), leisure activities, and performance at work/school**
- **The majority of patients reported improvements across all quality-of-life domains, irrespective of chronic migraine (CM) or episodic migraine (EM) status**
- **Limitations: Results may be limited by recall and participation bias; however, the sample was representative of the overall treatment population, and results were similarly distributed regardless of diagnosis (CM vs EM) or dosing regimen received (quarterly vs monthly)**

INTRODUCTION

- Patients with migraine often experience severe impairments across various occupational, social, and family domains, with over half of patients requiring bed rest during their attacks[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 difficult-to-treat population of adults with migraine and documented inadequate response to 2 to 4 classes of migraine preventive medications

OBJECTIVE

- To examine the patient-reported impact of fremanezumab treatment on social interactions, work and/or school performance, and leisure activities, which was retrospectively evaluated as part of a web-based questionnaire in a subpopulation of migraine patients who completed a 52-week extension study

METHODS

Study Design

- In the 52-week extension study, adults ≥18 years of age with CM or EM were randomized:

Quarterly fremanezumab (675 mg) | **Monthly fremanezumab (225 mg)***

*Some CM patients received a loading dose of 675 mg fremanezumab in the monthly arm.

- All patients were blinded to treatment received during the extension study
- Patients were recruited at 41 US extension study sites
- This study was approved by institutional review boards, and all patients provided written informed consent prior to participation in the study

Study Assessments

- From 1 to 24 months after the last extension study visit, patients completed an online patient experience survey (~20-40 minutes)
- As part of that retrospective survey, patients reported impact of fremanezumab treatment on social interactions, work and/or school performance, and leisure activities, based on the questions shown in **Table 1**
  - Improvement was defined as a score of ≥6 for all survey questions presented here
  - Statistical analysis: Continuous variables were expressed as means, while categorical variables were expressed as number and percentage

Table 1. Survey Questions and Response Options to Evaluate Quality of Life

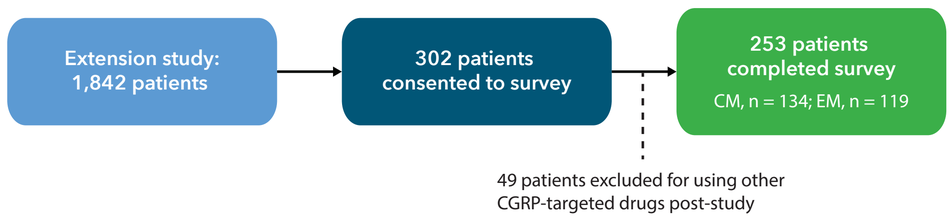
Compared to the 3-month baseline period before the first injection, on a scale of 0 to 10, where 0 is significantly less and 10 is significantly more, how much less or more time did you spend with friends and family while you were taking the study medicine?											
Significantly less					No difference						Significantly more
0	1	2	3	4	5	6	7	8	9	10	
Compared to the 3-month baseline period before the first injection, on a scale of 0 to 10, where 0 is significantly less and 10 is significantly more, how much change did you experience in the quality of time you spent with your friends and family while you were taking the study medicine?											
Significantly less					No difference						Significantly more
0	1	2	3	4	5	6	7	8	9	10	
Compared to the 3-month baseline period before the first injection, on a scale of 0 to 10, where 0 is significantly less and 10 is significantly more, how much less or more were you able to attend work or school while you were taking the study medicine?											
Significantly less					No difference						Significantly more
0	1	2	3	4	5	6	7	8	9	10	
Compared to the 3-month baseline period before the first injection, on a scale of 0 to 10, where 0 is significantly worse and 10 is significantly better, how did your work or school performance change while you were taking the study medicine?											
Significantly worse					No difference						Significantly better
0	1	2	3	4	5	6	7	8	9	10	
Compared to the 3-month baseline period before the first injection, on a scale of 0 to 10, where 0 is significantly worse and 10 is significantly better, how much did your ability to perform household activities and chores change while you were taking the study medicine?											
Significantly worse					No difference						Significantly better
0	1	2	3	4	5	6	7	8	9	10	
Compared to the 3-month baseline period before the first injection, on a scale of 0 to 10, where 0 is significantly less and 10 is significantly more, how much less or more could you participate in leisure and personal activities (ie, hobbies) while you were taking the study medicine?											
Significantly less					No difference						Significantly more
0	1	2	3	4	5	6	7	8	9	10	
Compared to the 3-month baseline period before the first injection, on a scale of 0 to 10, where 0 is significantly less and 10 is significantly more, how much less or more were you able to enjoy leisure and personal activities while you were taking the study medicine?											
Significantly less					No difference						Significantly more
0	1	2	3	4	5	6	7	8	9	10	

RESULTS

Patients

- 253 patients from the extension study completed the survey (**Figure 1**)
- All patients received active treatment during the extension study; 134 also received fremanezumab during a prior phase 3 study

Figure 1. Study design for recruitment of the survey population.



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

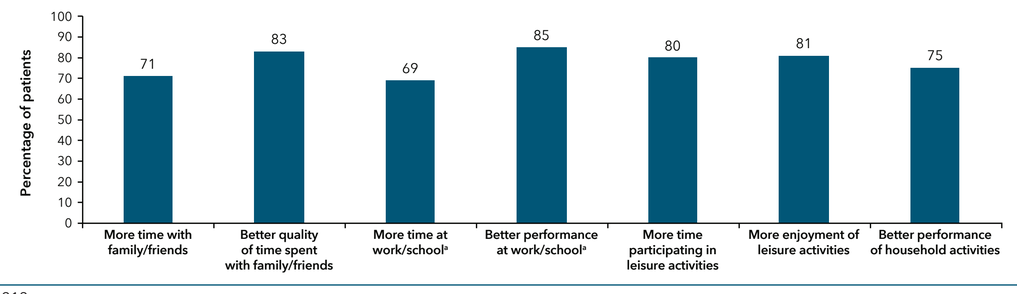
Table 2. Baseline Demographics of Patients in Migraine Survey Study and Overall Long-term Study Populations

	Migraine patient survey study population N = 253		Overall long-term study population N = 1,890	
Characteristic	EM n = 119	CM n = 134	EM n = 780	CM n = 1,110
Age, years, mean	46.9	45.2	44.0	43.1
Female sex, %	87	90	86	88
Quarterly/monthly dosing, %	52[a]/48[a]		51/49	50/50
Employment/school status, %			Not available	
Full time	63	63		
Part time	18	21		
Not employed for pay	18	16		
Student	7	13		

EM, episodic migraine; CM, chronic migraine.
[a]Data available only for the overall population (including EM and CM patients).

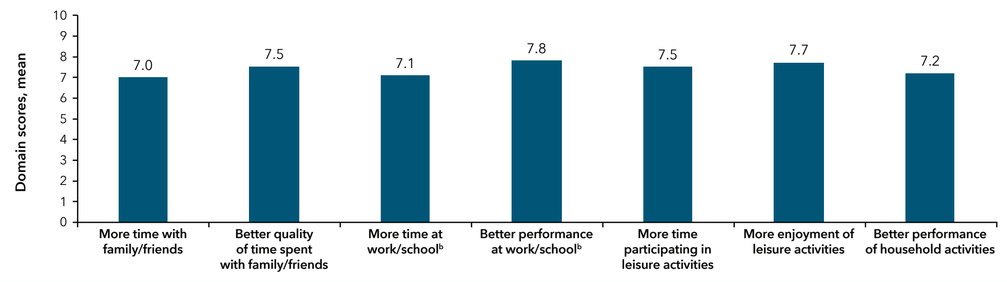
- Demographic and baseline characteristics were well balanced across treatment groups and representative of the general migraine population (**Table 2**)

Figure 2. Proportion of patients overall who reported improvements in psychosocial and quality-of-life domains as compared to baseline (N = 253).



[a]n = 213.

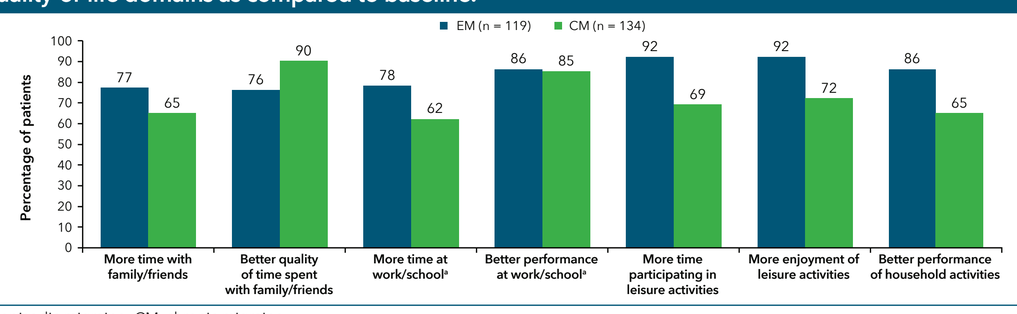
Figure 3. Patient-reported ratings for psychosocial and quality-of-life domains as compared to baseline for all patients (N = 253).[a]



[a]Domains were rated on a 10-point scale; 0 = significantly less/worse, 10 = significantly more/better.
[b]n = 213.

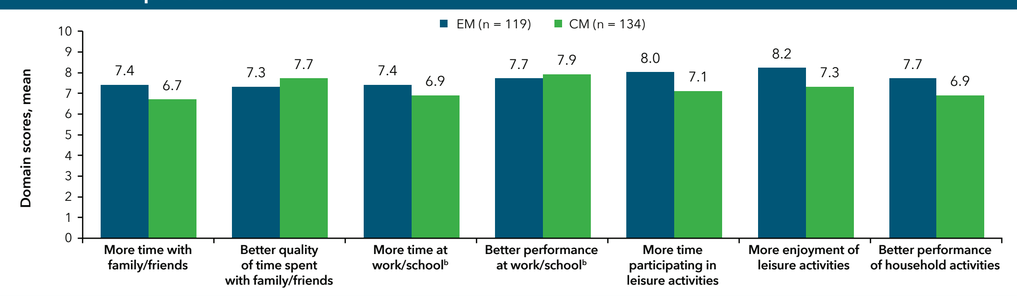
- When asked about their experience while taking fremanezumab versus the baseline period before the trial, the majority of patients overall reported improvement across all psychosocial and quality-of-life domains (**Figure 2** and **Figure 3**)

Figure 4. Proportion of EM and CM patients who reported improvements in psychosocial and quality-of-life domains as compared to baseline.



EM, episodic migraine; CM, chronic migraine.
[a]EM, n = 98; CM, n = 115.

Figure 5. Patient-reported ratings for psychosocial and quality-of-life domains as compared to baseline for EM and CM patients.[a]



[a]Domains were rated on a 10-point scale; 0 = significantly less/worse, 10 = significantly more/better.
[b]n = 213.

- Although the majority of CM and EM patients reported improvement across all these domains, higher proportions of EM patients reported improvements as compared to CM patients, except for the "better quality of time spent with family/friends" domain (**Figure 4** and **Figure 5**)

References

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Disclosures

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