Reductions in Migraine and Headache Days After Initiating Fremanezumab for Patients With Migraine and Prior Use of Another Monoclonal Antibody Targeting the CGRP Pathway in a US Real-world Setting

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Conclusions

- In this real-world study of migraine patients who had previously discontinued another monoclonal antibody (mAb) targeting the calcitonin gene-related peptide (CGRP) pathway (CGRP pathway mAb; targeting CGRP or the CGRP receptor [CGRP-R]), fremanezumab resulted in sustained clinically meaningful reductions in the monthly average number of migraine days (MMD) and monthly average number of headache days (MHD) over up to 6 months
- Reductions in MMD and MHD were similar in patients with and without prior treatment with a CGRP pathway mAb (CGRP mAb or CGRP-R mAb), suggesting that patients who failed a prior CGRP pathway mAb may still potentially achieve good effectiveness with fremanezumab

Introduction

- Fremanezumab, a fully humanized mAb (IgG2Δa) that selectively targets CGRP,[1] is US Food and Drug Administration approved for the preventive treatment of migraine in adults[2]
- Patients with inadequate response to 1 CGRP pathway mAb (CGRP mAb or CGRP-R mAb) may switch to another CGRP pathway mAb
- Limited real-world data are available on the effectiveness in terms of clinical outcomes in patients who switch from another CGRP pathway mAb to fremanezumab

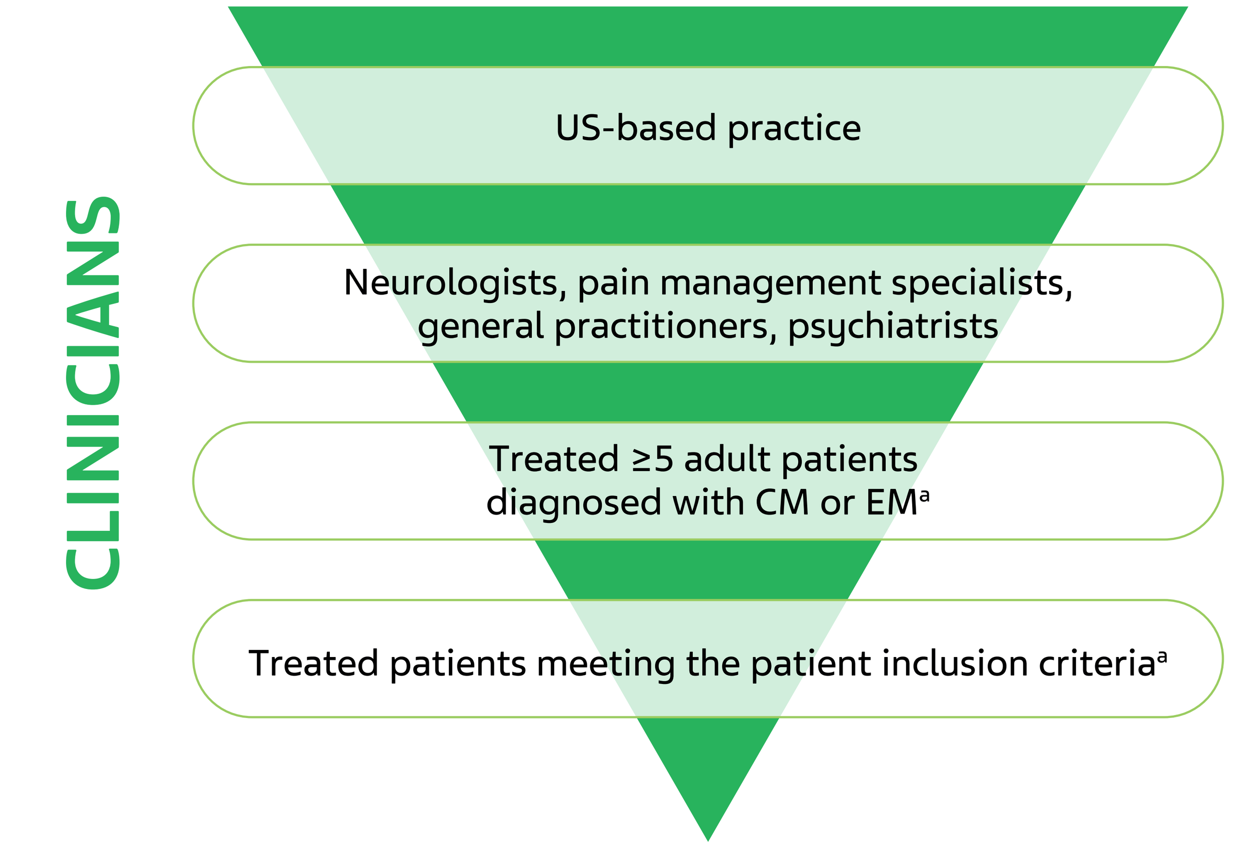
Objective

- To assess the effectiveness of fremanezumab in reducing MMD and MHD over a period of up to 6 months in adult migraine patients who had previously discontinued another CGRP pathway mAb

Methods

Clinicians

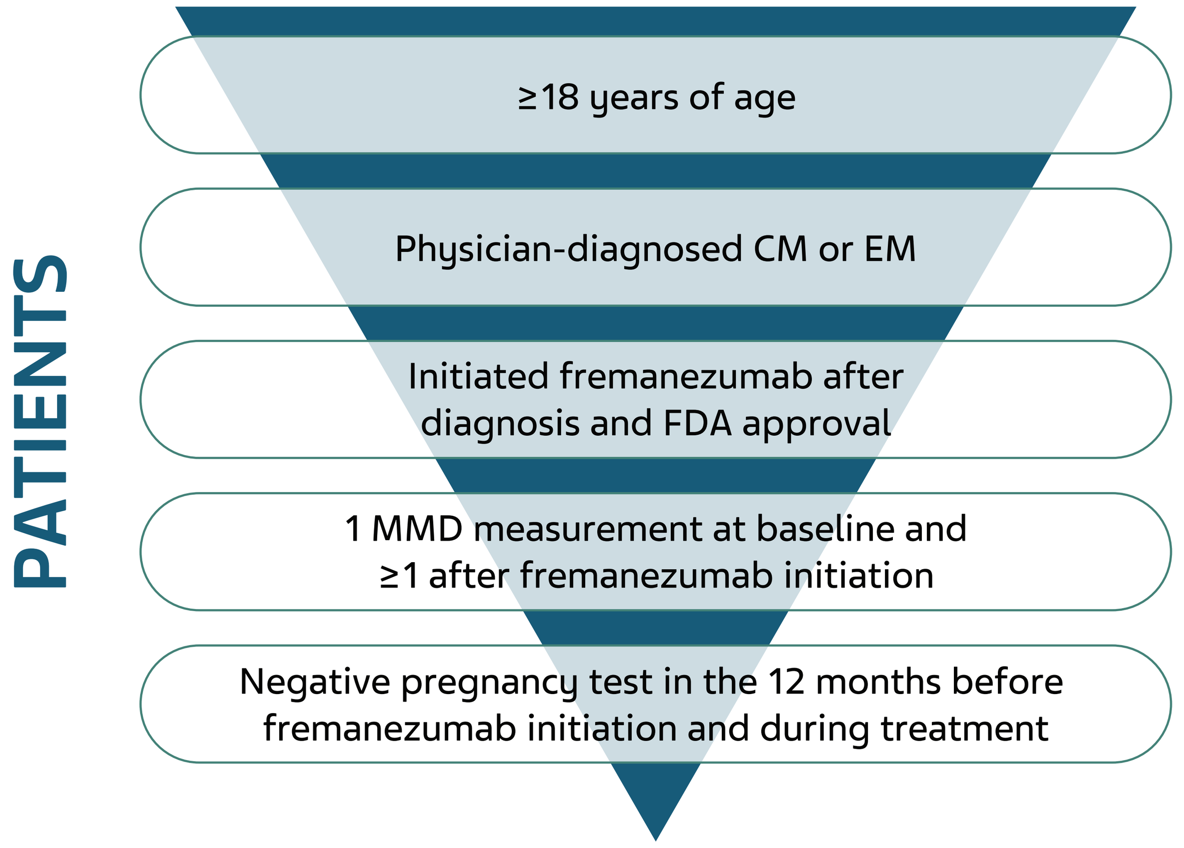
Figure 1. Clinician inclusion criteria.



CM, chronic migraine; EM, episodic migraine.
[a]In the past year.

Patients

Figure 2. Patient inclusion criteria.

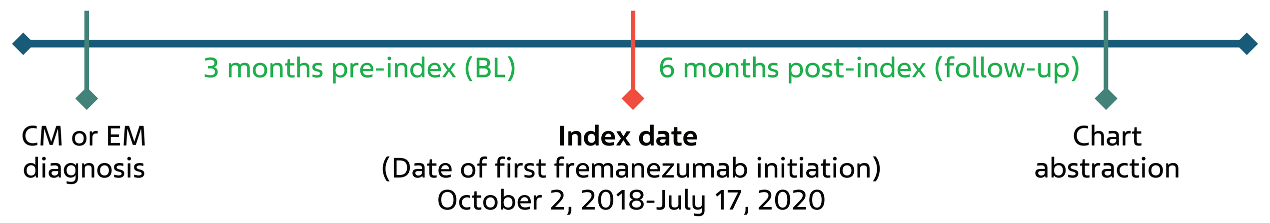


CM, chronic migraine; EM, episodic migraine; FDA, US Food and Drug Administration; MMD, monthly average number of migraine days.

- US-based clinicians treated patients who met the study's inclusion criteria (Figures 1 and 2)

Study Design

Figure 3. Study design and dosing for CM and EM patients.



CM, chronic migraine; EM, episodic migraine; BL, baseline.

- Institutional review board–approved, noninterventional, retrospective, online clinician panel–based chart review (Figure 3)
- The clinician extracted chart data for eligible patients and entered it into the provided electronic case report form

Study Assessments

- Changes in MMD and MHD in subgroups of patients with and without prior CGRP pathway mAb exposure were analyzed

Results

Table 1. Reasons for Discontinuing Prior CGRP Pathway mAb

Reasons for switching from a prior CGRP pathway mAb, n (%)[a]	All patients (n = 92[b])
Inadequate response to treatment	62 (67.4)
Side effects	30 (32.6)
Insurance coverage	18 (19.6)
Option of quarterly dosing	15 (16.3)
Availability of free samples	14 (15.2)
Long-acting profile of fremanezumab	13 (14.1)
Preference indicated by the patient	13 (14.1)
Wearing off prior to the next injection	10 (10.9)
Options of both monthly and quarterly dosing	10 (10.9)
Participation in clinical trial	2 (2.2)
Speed of onset of mediation	2 (2.2)

CGRP, calcitonin gene-related peptide; mAb, monoclonal antibody.
[a]1 (1.1%) patient reported switching due to other medical reasons, and 1 (1.1%) patient reported switching due to other nonmedical reasons.
[b]Patients who had discontinued a prior CGRP pathway mAb and provided a reason for prior discontinuation.

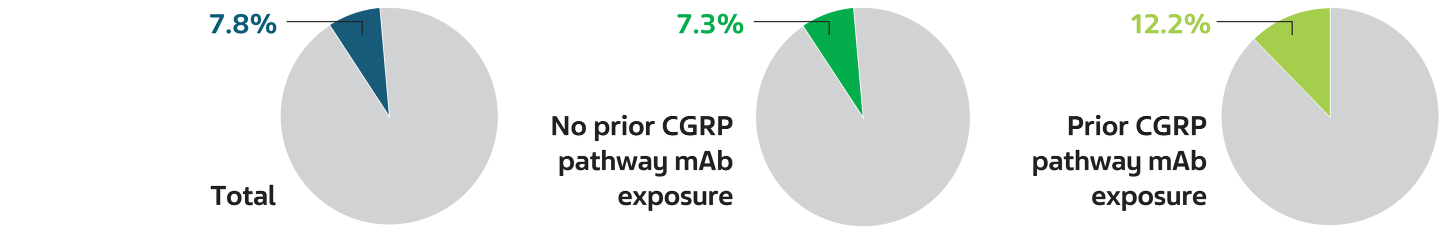
- In this subgroup of patients who discontinued a prior CGRP pathway mAb (9.8% [98/1,003]), the most common reasons for discontinuing that treatment were inadequate response to treatment and side effects (Table 1)

Table 2. Patient Baseline Characteristics

Characteristic	All patients (n = 1,003)	No prior CGRP pathway mAb exposure (n = 905)	Prior CGRP pathway mAb exposure (n = 98)
Age at index date (years), mean (SD)	39.7 (12.4)	39.3 (12.4)	43.3 (12.2)
Female, n (%)	760 (75.8)	683 (75.5)	77 (78.6)
Duration of follow-up (months), mean (SD)	7.1 (4.4)	7.1 (4.4)	7.2 (4.7)
BL MMD, mean (SD)	12.7 (6.4)	12.7 (6.4)	13.1 (6.2)
BL MHD, mean (SD)	14.0 (8.0)	14.0 (8.0)	14.6 (7.9)
Prior preventive treatment failures, n (%)[a,b]			
0	60 (6.0)	59 (6.5)	1 (1.0)
1	111 (11.1)	102 (11.3)	9 (9.2)
2	246 (24.5)	229 (25.3)	17 (17.3)
3	282 (28.1)	265 (29.3)	17 (17.3)
4	161 (16.1)	147 (16.2)	14 (14.3)
5	56 (5.6)	44 (4.9)	12 (12.2)
≥6	87 (8.7)	59 (6.5)	28 (28.6)
Common comorbidities, n (%)[c]			
Insomnia	196 (19.5)	169 (18.7)	27 (27.6)
Allergies	158 (15.8)	139 (15.4)	19 (19.4)
Neck pain	155 (15.5)	127 (14.0)	28 (28.6)
Hypertension	143 (14.3)	125 (13.8)	18 (18.4)
Back pain	138 (13.8)	118 (13.0)	20 (20.4)
Obesity	137 (13.7)	117 (12.9)	20 (20.4)
MDD	134 (13.4)	112 (12.4)	22 (22.4)
GAD	120 (12.0)	98 (10.8)	22 (22.4)
Chronic pain	111 (11.1)	89 (9.8)	22 (22.4)

CGRP, calcitonin gene-related peptide; mAb, monoclonal antibody; SD, standard deviation; BL, baseline; MMD, monthly average number of migraine days; MHD, monthly average number of headache days; MDD, major depressive disorder; GAD, generalized anxiety disorder.
[a]These numbers did not include the prior CGRP pathway mAb.
[b]Most of the previous treatments were oral migraine preventive medications.
[c]Incidence ≥15% in the overall, no prior CGRP pathway mAb, or prior CGRP pathway mAb groups.

Figure 4. The proportion of patients who discontinued fremanezumab.

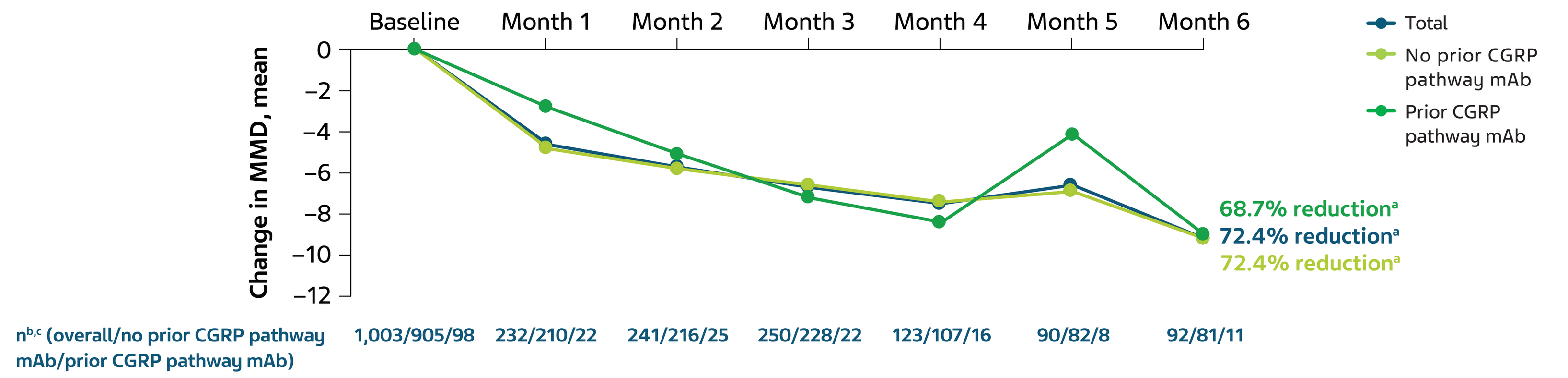


CGRP, calcitonin gene-related peptide; mAb, monoclonal antibody.

- The proportion of patients who discontinued fremanezumab was low (Figure 4)
  — The most common reason for treatment discontinuation was poor response to treatment

Effectiveness

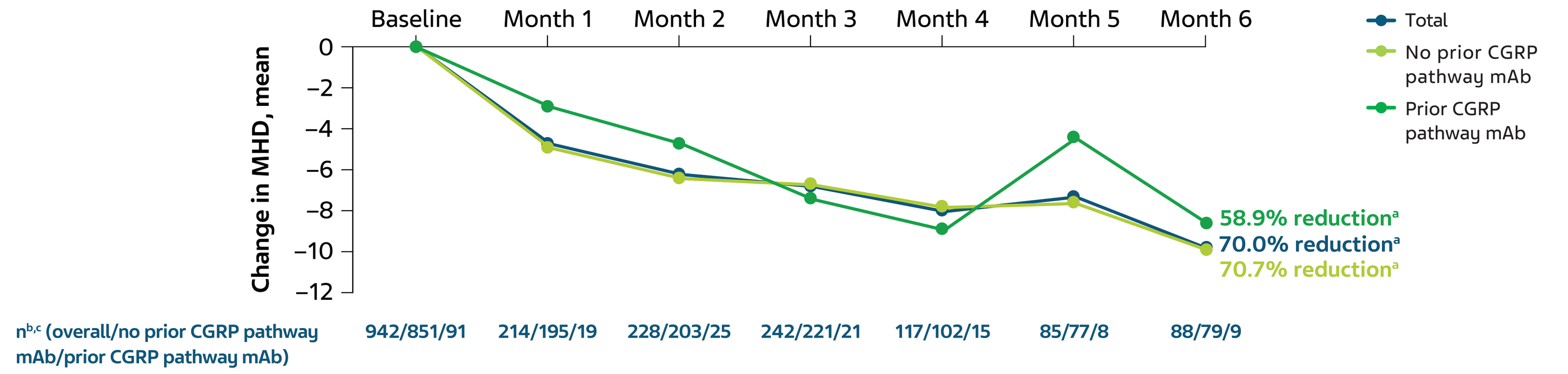
Figure 5. Change in MMD over 6 months.



MMD, monthly average number of migraine days; CGRP, calcitonin gene-related peptide; mAb, monoclonal antibody.
[a]Percent reduction from baseline.
[b]Number of patients with available assessment at each time point.
[c]The decline in MMD responses over time was likely not due to treatment discontinuation but was potentially due to missed follow-up appointments or limited recording of outcomes during telehealth visits.

- Fremanezumab treatment resulted in sustained reductions in mean MMD from baseline in patients with prior CGRP pathway mAb exposure over 6 months (Figure 5)
  — Mean reductions in MMD did not differ significantly for the prior CGRP pathway mAb group and the no prior CGRP pathway mAb group

Figure 6. Change in MHD over 6 months.



MHD, monthly average number of headache days; CGRP, calcitonin gene-related peptide; mAb, monoclonal antibody.
[a]Percent reduction from baseline.
[b]Number of patients with available assessment at each time point.
[c]The decline in MHD responses over time was likely not due to treatment discontinuation but was potentially due to missed follow-up appointments or limited recording of outcomes during telehealth visits.

- Fremanezumab treatment resulted in sustained reductions in mean MHD from baseline in patients with prior CGRP pathway mAb exposure over 6 months (Figure 6)
  — Mean reductions in MHD did not differ significantly for the prior CGRP pathway mAb group and the no prior CGRP pathway mAb group

Presented at Virtual ISPOR Europe 2021; 30 November-3 December 2021.

Disclosures: M.T. Driessen, S.F. Thompson, M. Seminerio, and K. Carr are employees of Teva Pharmaceuticals. J.M. Cohen is a former employee of Teva Pharmaceuticals. O. Patterson-Lomba, F. Mu, R. Sun, T. Totev, E. Yim, and R. Ayyagari are employees of Analysis Group, which received funding for these analyses from Teva Pharmaceuticals.

Acknowledgments: This study was funded by Teva Pharmaceuticals. Medical writing and editorial support were provided by Soan Kim, PharmD, of Cello Health Communications/MedErgy, and were funded by Teva Pharmaceuticals USA, Inc.

References: 1. Walter S, Bigal ME. *Curr Pain Headache Rep.* 2015;19(3):6. 2. AJOVY® (fremanezumab-vfrm) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; Revised 2020.