Effectiveness and Safety of Fremanezumab for Migraine Prevention Over 24 Months of Treatment: Final Analysis From the Italian Cohort of the PEARL Study

Poster number: 48

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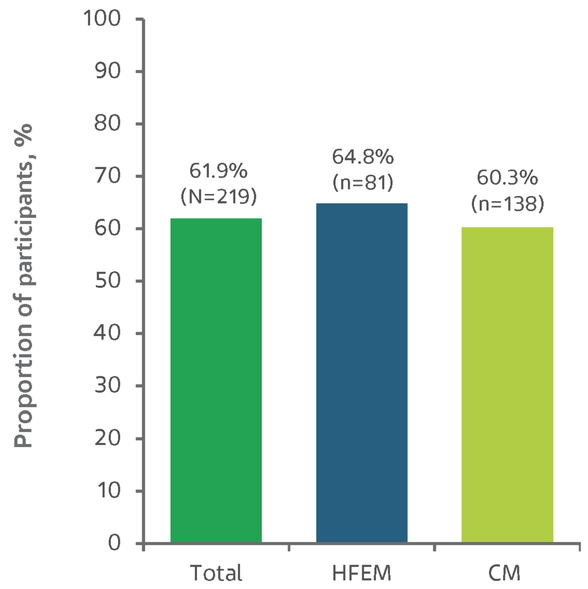
Objective: to evaluate fremanezumab effectiveness and safety in Italian adults with high-frequency episodic migraine (HFEM) or chronic migraine (CM) over 24 months of follow-up

Background

- Fremanezumab, a humanized monoclonal antibody that selectively binds calcitonin gene-related peptide, is approved for the preventive treatment of migraine in adults with ≥4 monthly migraine days (MMD)[1]
- For the reimbursement of fremanezumab in Italy, patients must experience ≥8 MMD, have a Migraine Disability Assessment score of ≥11, and have previously failed ≥3 preventive migraine treatments[2]
- The Pan-European Real Life (PEARL) study (EUPAS35111) was a prospective, observational, Phase 4 study designed to evaluate the real-world effectiveness, safety, and tolerability of fremanezumab in participants with EM or CM across 11 European countries[3]
- This analysis of PEARL reports data from Italian participants after 24 months of follow-up

In total, 61.9% of participants achieved ≥50% average MMD reduction from baseline during the 6-month period after fremanezumab initiation, with sustained reductions in average MMD observed up to Month 24

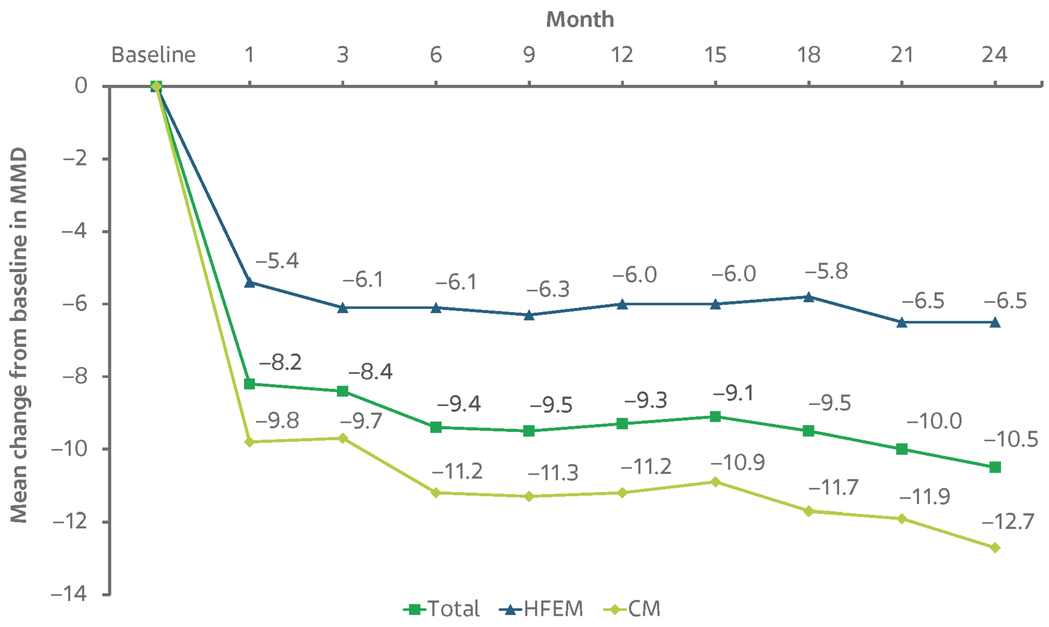
Figure 1. Proportion of Participants Reaching ≥50% Average MMD Reduction From Baseline During the 6-Month Period After Fremanezumab Initiation, by Migraine Type



	Total	HFEM	CM
Participants, n	354	125	229

CM, chronic migraine; HFEM, high-frequency episodic migraine; MMD, monthly migraine days.

Figure 2. Mean Change From Baseline in Average MMD at Months 1, 3, 6, 9, 12, 15, 18, 21, and 24, by Migraine Type



	Baseline	1	3	6	9	12	15	18	21	24
Total, N	354	354	349	337	329	319	293	283	275	233
HFEM, n	125	125	123	119	117	116	107	104	99	82
CM, n	229	229	226	218	212	203	186	179	176	151

The drop in data at post-baseline time-points is due to participants who prematurely discontinued the study. Missing data are excluded. CM, chronic migraine; HFEM, high-frequency episodic migraine; MMD, monthly migraine days.

Conclusion

- Treatment with fremanezumab led to sustained reductions in MMD and monthly days with acute medication use in Italian participants with HFEM and CM throughout the 24-month study period
- No new safety signals were observed
- These long-term data support the effectiveness and safety of fremanezumab for migraine prevention in this real-world population[4]

Methods

- Eligible participants were adults with HFEM or CM receiving monthly (225 mg) or quarterly (675 mg) fremanezumab
- As per routine disease management, participants were expected to schedule physician visits every 3 months and maintain a daily headache diary
- The primary endpoint was the proportion of participants with a ≥50% reduction in average MMD during the 6-month period after fremanezumab initiation
- Secondary endpoints included mean changes from baseline in average MMD and in monthly average number of days with acute headache medication use at Months 1, 3, 6, 9, 12, 15, 18, 21, and 24
- Safety was assessed through adverse event reporting

Demographics

- The overall cohort comprised 354 participants enrolled in 30 Italian centers
  - All enrolled participants were included in the effectiveness analysis, **Table 1**

Table 1. Baseline Characteristics

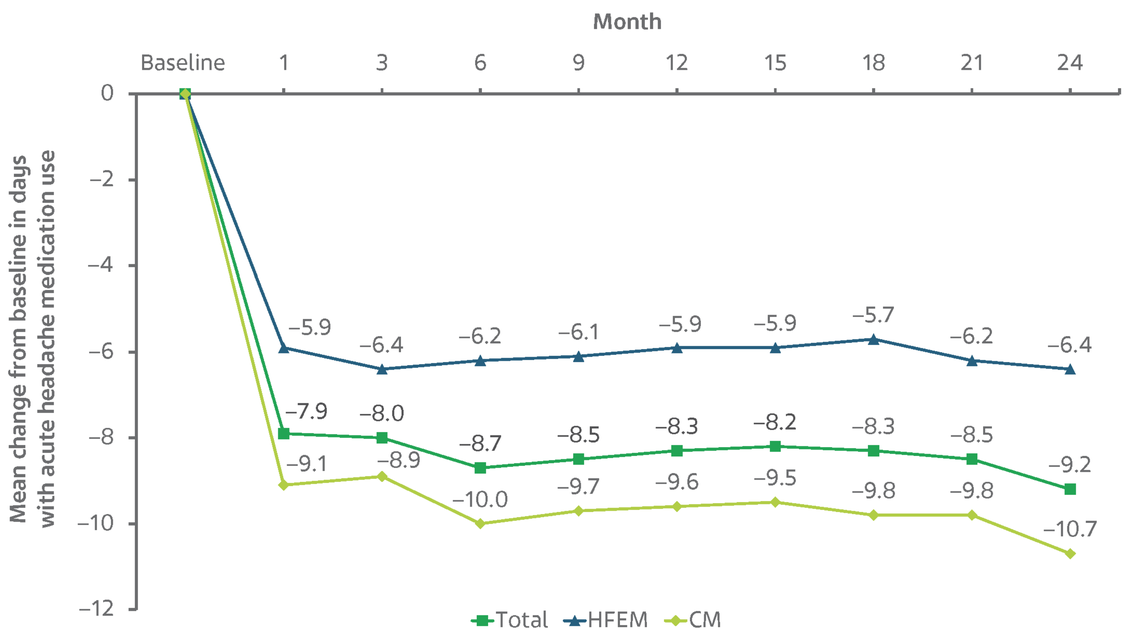
	Overall cohort (N=354)
Age, years, mean (SD)	
20–45	133 (37.6)
45–65	189 (53.4)
>65	30 (8.5)
Female, n (%)	291 (82.2)
CM, n (%)	229 (64.7)
Time since diagnosis, years, n (%)	
<10	96 (27.1)
10–20	80 (22.6)
>20	87 (24.6)
Missing	91 (25.7)
MMD, mean (SD)	15.6 (6.6)
Monthly days with acute headache medication use, mean (SD)	13.0 (6.5)

CM, chronic migraine, MMD, monthly migraine days; SD, standard deviation.

Additional results

- Sustained reductions from baseline in days of acute headache medication use were observed across Months 1 to 24, **Figure 3**

Figure 3. Mean Change From Baseline in Days With Acute Headache Medication Use at Months 1, 3, 6, 9, 12, 15, 18, 21, and 24, by Migraine Type



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- No new safety signals were observed with fremanezumab, despite the long duration of treatment participants received in the study

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Disclosures

G. Vaghi has received personal fees from Lundbeck and travel grants from Teva Pharmaceuticals. M. Bandettini di Poggio and M. Marcosano have no conflicts to declare. A. Granato has received travel grants, honoraria for advisory board, speaker panels, or clinical investigation studies from Allergan/AbbVie, Eli Lilly, Novartis, and Teva Pharmaceuticals. D. Mascarella has received educational grants from Eli Lilly and travel grants from AbbVie, Eli Lilly, and Teva Pharmaceuticals. F. Frediani has collaborated with and received grants from AbbVie, Cristalfarma, Eli Lilly, Lundbeck, Pfizer, Teva Pharmaceuticals, and UCBM. P. Kokturk is an employee of Teva Pharmaceuticals.

References

1. European Medicines Agency. AJOVY® (fremanezumab) [summary of product characteristics]. Available at: https://www.ema.europa.eu/en/documents/product-information/ajovy-epar-product-information_en.pdf (accessed September 2025).
2. Italian Medicines Agency. 2020. Available at: https://www.aifa.gov.it/en/-/attivazione-web-e-pubblicazione-schede-di-monitoraggio-registro-aimovig (accessed September 2025).
3. Ashina M, et al. *Pain Manag* 2021;11:647–654.
4. Iannone LF, et al. Presented at the 10th European Academy of Neurology (EAN) Congress; Helsinki, Finland, 29 June–2 July 2024 (EPV-367).

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