

LONG-TERM EFFECTIVENESS AND SAFETY OF FREMANEZUMAB FOR MIGRAINE PREVENTION: 24-MONTH OUTCOMES FROM THE ITALIAN COHORT OF THE PEARL STUDY

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Background. Fremanezumab is a calcitonin gene-related peptide pathway monoclonal antibody approved for the prevention of episodic (EM) and chronic migraine (CM). In Italy, fremanezumab reimbursement is subject to Italian Medicines Agency criteria (≥8 monthly migraine days [MMD], a Migraine Disability Assessment [MIDAS] score of ≥11 before treatment and ≥3 prior preventive treatment failures). Here, we report effectiveness and safety of fremanezumab for migraine prevention in Italian participants enrolled in the observational, Phase 4 Pan-European Real Life (PEARL; EUPAS35111) study after 24 months of follow-up.

Methods. Eligible participants were adults with high-frequency EM (HFEM) and CM receiving monthly (225 mg) or quarterly (675 mg) fremanezumab in routine clinical practice. A mandatory ≥1 month treatment discontinuation period occurred following 12 months of continuous treatment. The primary endpoint was the proportion of participants achieving ≥50% reduction in MMD during the 6 months following fremanezumab initiation. Secondary endpoints included mean change from baseline in MMD at Months 1 and 24, and mean MIDAS scores over 24 months. Safety was assessed through adverse event (AE) reporting.

Results. This analysis included 354 participants (HFEM, n=125; CM, n=229) from 30 Italian centres (female, 82.2%; CM, 64.7%; baseline MMD, 15.6 days). In total, 61.9% (n=219/354) of participants achieved ≥50% reduction in MMD during the 6-month period after fremanezumab initiation. Mean change from baseline in MMD was sustained from Month 1 (total, –8.2; HFEM, –5.4; CM, –9.8) to Month 24 (total, –10.5; HFEM, –6.5; CM, –12.7). In participants with documented cessation and reinitiation, mean MIDAS scores decreased from 93.7 at baseline (HFEM, 67.8; CM, 107.8) to 22.0 at Month 12 after fremanezumab initiation (HFEM, 14.0; CM, 26.0), and from 37.5 at baseline of reinitiation (HFEM, 29.9; CM, 42.6) to 25.3 at Month 12 after reinitiation (HFEM, 11.7; CM, 31.5). Drug-related AEs were reported in 62/354 (17.5%) participants, with 2/354 (0.6%) reporting drug-related serious AEs and 4/354 (1.1%) reporting AEs that led to discontinuation.

Conclusions. These results underscore the long-term effectiveness and safety of fremanezumab for the preventive treatment of HFEM and CM and the importance of continued treatment now that treatment pauses are no longer mandated.