PEARL study protocol: a real-world study of fremanezumab effectiveness in patients with chronic or episodic migraine

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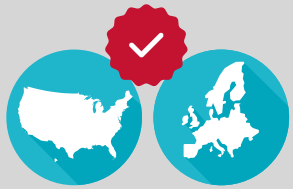
Fremanezumab, a humanized monoclonal antibody (IgG2Δa) that selectively targets calcitonin gene-related peptide (CGRP), is approved in Europe for migraine prevention in adults with ≥4 migraine days/month and in the USA for the preventive treatment of migraine in adults.



Approved in the USA & Europe

The PEARL study is planned to be conducted in ~100 centers in 11 European countries (Czech Republic, Denmark, Finland, Greece, Italy, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom), with an estimated sample size of 1100 patients.

~100 Centers

11 European countries

1100 Patients

Real-world data

P4 Phase IV

24 24-month study

Multicenter

The Pan-European Real Life (PEARL) study is an ongoing, 24-month, multicenter, pan-European, prospective, observational, Phase IV real-world study being conducted in patients with CM or EM.

KEY ELIGIBILITY CRITERIA

- Male and female patients aged ≥18 years who have been diagnosed with CM or EM.
- Patients have been prescribed fremanezumab at SC doses of 225 mg monthly or 675 mg quarterly, per the SmPC.
- Patients maintaining a daily headache diary as part of their routine disease management with ≥21 days of diary data in the 28 days prior to fremanezumab treatment initiation.
- Patients must be willing to record information on their headache duration, severity and characteristics in their diary throughout the study.

PRIMARY END POINT:

Proportion of patients reaching a clinically meaningful, ≥50% reduction in the monthly number of migraine days during the first 6 months of fremanezumab treatment.

50%

SECONDARY EFFECTIVENESS END POINTS:

- Changes from baseline in the monthly number of migraine days, in disability severity, and in the monthly number of days of use of acute headache medication with fremanezumab treatment.
- Adherence and persistence with fremanezumab treatment over 24 months, along with reasons for and outcomes of fremanezumab cessation and re-initiation.
- Real-world safety and tolerability during 24 months of treatment with fremanezumab.

GLOSSARY:

CM: Chronic migraine; EM: Episodic migraine; SmPC: Summary of product characteristics; SC: Subcutaneous.