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EPTINEZUMAB IMPROVED PATIENT-REPORTED OUTCOMES AND QUALITY OF LIFE IN PATIENTS WITH MIGRAINE AND PRIOR PREVENTIVE TREATMENT FAILURES[1]

Peter J Goadsby, Piero Barbanti, Giorgio Lambru, Anders Ettrup, Cecilie Laurberg Christoffersen, Mette Krog Josiassen, Ravinder Phul, Bjørn Sperling

VYEPTI™ (eptinezumab) is indicated for the prophylaxis of migraine in adults who have at least 4 migraine days per month.[2] The recommended dose is 100 mg administered by intravenous infusion every 12 weeks.[2]

CONTEXT[1,3]

In the phase 3b, multicentre, multi-arm double-blind, placebo-controlled **DELIVER** study, eptinezumab reduced migraine and headache frequency and severity and acute medication use compared to placebo in adults with migraine and 2–4 prior preventive treatment failures.[3] This is a summary of a sub-analysis to investigate the effects of eptinezumab on patient-reported outcomes (PROs) reflecting quality of life and functioning in the placebo-controlled phase of the DELIVER study.[1] Refer to the full publication for more details.

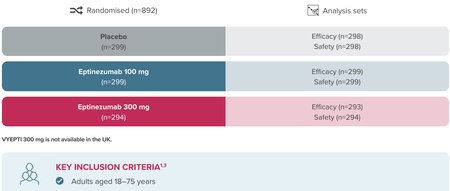
KEY QUESTION[1]

What are the effects of eptinezumab on PROs reflecting quality of life and functioning in patients with documented prior preventive treatment failures arising from inadequate efficacy, tolerability, or contraindication reasons?

METHODOLOGY[1,3]

- Multicentre, double-blind, randomised, placebo-controlled, parallel-group, phase 3b clinical trial
- The 76-week adaptive design study comprised a 24-week placebo-controlled period and a 48-week dose-blinded extension period
- A total of 1,369 patients were screened for study inclusion. 892 were randomised to receive treatment and 865 completed the placebo-controlled treatment period[3]

PATIENT DISPOSITION[1,3]



VYEPTI 300 mg is not available in the UK.

KEY INCLUSION CRITERIA[1,3]

- Adults aged 18–75 years
- Diagnosis at/before 50 years of age
- History of migraine for ≥12 months before screening
- CM or EM diagnosis per ICHD criteria
- CM criteria: Experienced ≥15 headache days and ≥8 migraine days during the 28-day screening period
- EM criteria: Experienced up to 14 headache days and ≥4 migraine days during the 28-day screening period
- Two-to-four different prior preventive migraine medication failures (i.e., propranolol/ metoprolol, topiramate, amitriptyline, flunarizine, candesartan, valproate or divalproex, or botulinum toxins A or B) in the past 10 years
- Failure due to inadequate efficacy (≥3 months), tolerability (i.e., discontinuation due to AEs), or contraindications (i.e., ineligibility due to medical reasons)

KEY EXCLUSION CRITERIA[1,3]

- Previous treatment failure of agent targeting the CGRP pathway

DELIVER PRIMARY ENDPOINT (eptinezumab vs placebo)[3]

Change from baseline in monthly migraine days (MMDs) over Weeks 1–12

PRO MEASURES – SUB-ANALYSIS (eptinezumab vs placebo)[1]

- PRO measures included the EQ-5D-5L, HIT-6, PGIC, PI-MBS and MSQ
- All PRO measures were administered at baseline (except PGIC) and Weeks 12 and 24 site visits prior to infusion
- The EQ-5D-5L and HIT-6 were also completed every 4 weeks between site visits

RESULTS[1,3]

DELIVER PRIMARY ENDPOINT

- In Weeks 1–12, eptinezumab 100 mg significantly reduced the number of MMDs compared with placebo[3]

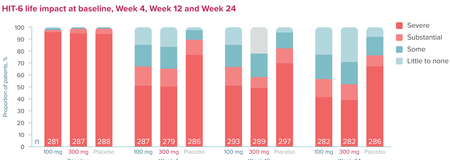
PRO OUTCOMES[1]

- Eptinezumab improved EQ-5D-5L VAS score compared with placebo as early as Week 4 (mean change in well-being numerically improved in the eptinezumab groups and numerically deteriorated in the placebo group)

Mean change from baseline in EQ-5D-5L VAS score

*p<0.05 vs placebo; **p<0.001.
Adapted from Goadsby PJ, *et al. Eur J Neurol.* 2023.

HIT-6 life impact at baseline, Week 4, Week 12 and Week 24



Adapted from Goadsby PJ, *et al. Eur J Neurol.* 2023.

- At Weeks 12 and 24, the percentages of patients with a ≥5-point reduction in HIT-6 total score were higher for both doses of eptinezumab compared with placebo (p<0.0001)
- Both doses of eptinezumab improved PGIC score compared with placebo (p<0.0001 at Weeks 4, 12 and 24) with >60% of patients reporting either "much improved" or "very much improved" at Week 24
- >50% of patients reported either "much improved" or "very much improved" on the PI-MBS scale at Weeks 12 and 24 (p<0.0001 vs placebo at both timepoints)
- Both doses of eptinezumab improved MSQ domain scores (role function restrictive, role function preventive and emotional function) from baseline by a greater amount than placebo at Weeks 12 and 24 (p<0.0001)

SAFETY & TOLERABILITY[3]

- Safety and tolerability have previously been described in full in the primary DELIVER publication
- In DELIVER, TEAEs were reported by 42% of patients receiving eptinezumab 100 mg and 40% of patients receiving placebo. TEAEs leading to study drug withdrawal occurred in 1 patient (<1%) receiving eptinezumab 100 mg and 1 patient (<1%) receiving placebo[3]
- Please refer to the primary publication for full safety data

LIMITATIONS[1]

- Most of the analyses included were not part of the statistical hierarchy; as such, the results must be interpreted with caution
- The individual outcome measures used themselves have limitations, in particular the EQ-5D-5L, which likely underestimates the impact for patients who didn't have a migraine on the day the measure was administered

CONCLUSIONS[1]

- Patients with two to four prior preventive treatment failures who received eptinezumab consistently reported greater improvement in PROs and quality of life, as well as reduced life impact, than patients who received placebo
- Benefits were observed as early as Week 4 and continued through Week 24

REFERENCES & ABBREVIATIONS

1. Goadsby PJ, *et al. Eur J Neurol.* 2023;30(4):1089–1098.
2. Lundbeck. VYEPTI. Summary of Product Characteristics.
3. Ashina M, *et al. Lancet Neurol.* 2022;21(7):597–607.

AE, adverse event; **CGRP,** calcitonin gene-related peptide; **CM,** chronic migraine; **EM,** episodic migraine; **EQ-5D-5L,** European Quality of Life 5-Dimension 5-Level; **HIT-6,** 6-item Headache Impact Test; **ICHD,** International Classification of Headache Disorders; **LS,** least squares; **MMDs,** monthly migraine days; **MSQ,** migraine-specific quality of life; **PGIC,** Patient's Global Impression of Change; **PI-MBS,** patient-identified most bothersome symptom; **PRO,** patient-reported outcome; **VAS,** visual analog scale.

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