

Press release

Valby, 1 October, 2026

Lundbeck announces headline results from Phase IV THRIVE trial evaluating VYEPTI® (eptinezumab) following inadequate response to prior CGRP-targeting preventive therapy

- Primary endpoint analysis of the clinical Phase IV THRIVE trial showed that 60% of participants reported being ‘much improved’ or ‘very much improved’ following treatment with eptinezumab
- Results provide prospective clinical data on the use of eptinezumab in adults with migraine following inadequate response to one prior CGRP-targeting preventive therapy
- Eptinezumab was generally well tolerated with no new safety signals identified in this population
- Full results from the trial will be presented at upcoming scientific congresses

Valby, Denmark, Thursday 1 October 2026 – H. Lundbeck A/S (Lundbeck) today announced headline results from the Phase IV interventional, open-label THRIVE trial (NCT06701526), evaluating eptinezumab in adults with migraine who had experienced an inadequate response to one prior calcitonin gene-related peptide (CGRP)-targeting preventive therapy.

THRIVE is the first interventional trial specifically designed to evaluate outcomes after treatment with eptinezumab in people with migraine who had experienced inadequate response to one previous CGRP-targeting preventive therapy. The trial addresses an important evidence gap, as there is currently limited clinical data to inform treatment sequencing for patients who received prior migraine preventive therapies.

In the THRIVE trial, participants received eptinezumab 100 mg at baseline, followed by dose escalation to 300 mg at week 12. At week 12, 44% of participants remaining in the trial reported being ‘much improved’ or ‘very much improved’ on the Patient Global Impression of Change (PGIC). At week 24, the trial’s primary endpoint, 60% of participants remaining in the trial reported being ‘much improved’ or ‘very much improved’.

“These results provide important prospective clinical trial data for people who continue to experience substantial migraine burden despite treatment with a prior CGRP-targeting preventive therapy,” said Tarek Samad, Executive Vice President and Head of Research and Development at Lundbeck. “THRIVE was designed to help answer a clinically relevant question about what may come next for these patients, and these encouraging results add to the growing body of evidence supporting eptinezumab in migraine prevention. This is an important part of our continued commitment to helping more people achieve better control of this disabling neurological disease.”

Reductions across monthly migraine days, monthly headache days, and acute medication use were also assessed, alongside measures of migraine-related burden. These findings will add further perspective to the overall improvement reported by participants on the PGIC. In addition,

eptinezumab was well tolerated with no new safety signals identified in this patient population experiencing previous inadequate response to CGRP-targeting treatments.

Full results from THRIVE will be submitted for presentation at a future scientific congress and publication in a peer-reviewed journal.

About migraine

Migraine is a complex and disabling neurological disease characterized by recurrent attacks of severe headache typically accompanied by an array of symptoms, including nausea, vomiting, and sensitivity to light and sound. The disease can have a profound impact on daily functioning, work productivity, family, and social relationships and quality of life.

Migraine is one of the most prevalent neurological diseases worldwide and remains a leading cause of disability, particularly among people under the age of 50.^{1,2} As migraine frequency and severity increase, attacks may become harder to control, contributing to greater disease burden and, without appropriate preventive management, progression to chronic migraine.³

Despite recent advances in migraine-specific prevention, some patients continue to experience substantial migraine burden after an inadequate response to CGRP-targeting preventive therapies. Real-world studies of anti-CGRP monoclonal antibodies and preventive gepants have reported treatment discontinuation rates of approximately 40–45%, with inadequate effectiveness among the main reasons for discontinuation.^{4,5}

About the THRIVE trial

The THRIVE trial was a 24-week, Phase IV, open-label, multicenter, interventional trial conducted in the United States evaluating the effectiveness and safety of eptinezumab in adults with migraine who had an inadequate response to one prior CGRP-targeting preventive therapy. The study enrolled 164 adults with at least eight monthly migraine days (MMD) who had previously received either a subcutaneous anti-CGRP monoclonal antibody or preventive gepant and had not received eptinezumab. All participants initiated eptinezumab 100 mg and subsequently escalated to 300 mg at Week 12 (147 participants received two infusions), and 84% (138/164) of participants completed the trial.

The primary endpoint was the proportion of participants reporting ‘much improved’ or ‘very much improved’ on the 7-point Patient Global Impression of Change (PGIC) scale (comprising ‘very much improved’, ‘much improved’, ‘minimally improved’, ‘no change’, ‘minimally worse’, ‘much worse’, or ‘very much worse’) at Week 24. Secondary endpoints included reductions in MMDs, ≥50% MMD responder rate, patient-reported outcomes assessing changes in migraine burden (including MIDAS, number of good days, brain fog as well as goal attainment scaling [GAS], a novel endpoint in migraine trials). Safety and tolerability of eptinezumab were evaluated through assessment of adverse events and vital signs during the trial.

About Vyepti® (eptinezumab)

Eptinezumab is a humanized monoclonal antibody that binds to CGRP and was intentionally designed for intravenous administration. The efficacy and safety of eptinezumab were evaluated in two Phase III clinical trials, PROMISE-1 in episodic migraine⁶ and PROMISE-2 in chronic

migraine.⁷ In both trials, eptinezumab met its primary endpoint of decrease in monthly migraine days (MMDs) over weeks 1-12.

The safety of eptinezumab was evaluated in more than 2,000 adult patients with migraine who received at least one dose of eptinezumab. The most common adverse reactions ($\geq 2\%$ and at least 2% or greater than placebo) in the clinical trials for the preventive treatment of migraine were nasopharyngitis and hypersensitivity. Approximately 8% of patients on 300 mg, 6% of patients on 100 mg and 6% of patients on placebo in PROMISE-1 and PROMISE-2 experienced nasopharyngitis. In PROMISE-1 and PROMISE-2, 1.9% of patients treated with eptinezumab discontinued treatment due to adverse reactions.

Since launch, the safety of eptinezumab has been evaluated in more than 5,000 adult patients with migraine who received at least one dose in the placebo-controlled clinical trials for the preventive treatment of migraine. Common adverse reactions were hypersensitivity and infusion-related reactions.

VYEPTI® (eptinezumab-jjmr) was approved by the U.S. Food and Drug Administration (FDA) for the preventive treatment of migraine in adults in February 2020, and in January 2022, eptinezumab was granted marketing authorization by the European Commission (EC) for the prophylaxis of migraine in adults who have at least four migraine days per month. Today, eptinezumab is launched in more than 30 markets worldwide.

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About H. Lundbeck A/S

Lundbeck is a biopharmaceutical company focusing exclusively on brain health. With more than 70 years of experience in neuroscience, we are committed to improving the lives of people with neurological and psychiatric diseases.

Brain disorders affect a large part of the world's population, and the effects are felt throughout society. With the rapidly improving understanding of the biology of the brain, we hold ourselves accountable for advancing brain health by curiously exploring new opportunities for treatments.

As a focused innovator, we strive for our research and development programs to tackle some of the most complex neurological challenges. We develop transformative medicines targeting people for whom there are few or no treatments available, expanding into neuro-specialty and neuro-rare from our strong legacy within psychiatry and neurology.

We are committed to fighting stigma and we act to improve health equity. We strive to create long term value for our shareholders by making a positive contribution to patients, their families and society as a whole.

Lundbeck has more than 5,000 employees in more than 20 countries and our products are available in more than 80 countries. For additional information, we encourage you to visit our corporate site www.lundbeck.com and connect with us via [LinkedIn](#).

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