Press release
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Lundbeck presents new real-world data highlighting meaningful improvements in patients severely impacted by migraine initiating Vyepti® (eptinezumab), at HCOP Annual Conference

- New six-month results from the Vyepti® (eptinezumab) 12-month, real-world INFUSE study presented at the 2026 Headache Cooperative of the Pacific (HCOP) Annual Conference, Ojai, California[1]
- The INFUSE study includes adults with migraine who had failed at least one preventive anti-calcitonin gene–related peptide (aCGRP) treatment[1]
- Clinically meaningful improvements reported across migraine frequency, responder rates and other patient-reported outcomes in adults switching to eptinezumab[1]

Valby, Denmark, 30 January 2026 – H. Lundbeck A/S (Lundbeck) today announced six-month data from the 12-month, real-world INFUSE study, evaluating the effectiveness of Vyepti® (eptinezumab) in adults with migraine who had failed at least one preventive anti-calcitonin gene–related peptide (aCGRP) treatment, at any time point previously. The findings, presented at the 2026 Headache Cooperative of the Pacific (HCOP) Annual Conference in California, USA (30–31 January), show improvements across multiple patient-reported outcomes in patients switching to intravenous (IV) eptinezumab, despite high disease burden.[1]

Migraine is the third most prevalent disease globally, and although multiple preventive treatment options are available, many patients continue to experience high disease burden due to insufficient efficacy or tolerability issues. Literature to date indicates that switching between subcutaneous (SC) aCGRP preventive therapies results in modest and variable improvement,[2-7] while evidence on the benefit of switching from SC or oral therapies to IV eptinezumab remains limited.

“These real-world data strengthen our confidence in eptinezumab’s ability to deliver meaningful improvements in migraine burden, not only in clinical trials, but in everyday clinical practice,” said Johan Luthman, EVP and Head of Research & Development at Lundbeck. “INFUSE demonstrates that patients receiving eptinezumab report consistent reductions in migraine frequency and improvements in everyday functioning, even in participants who previously experienced limited benefit from preventive aCGRPs.”

The INFUSE study is an ongoing observational, prospective study in which people with migraine were recruited through two Vyepti® Infusion Network partners in the US. This study includes adults in whom ≥1 preventive aCGRP had failed due to a lack of effectiveness or side effects, with no specific time frame between treatments required, according to protocol. This analysis reports the findings in participants who successfully completed a full six months of treatment with eptinezumab (n=111).[1] Safety data was not collected in the study, however reported via standard safety reporting channels.

After two infusions of eptinezumab, 75.7% of participants reported an improvement (any level) in migraine status (95% CI: 66.9%, 82.7%), as measured by the Patient Global Impression of Change Scale (PGIC) with 44.1% reporting "much improved," or "very much improved" (95% CI: 35.3%-53.4%). 44.1% of participants (95% CI: 35.3%-53.4%) reported a ≥50% reduction in monthly headache days (MHDs), with a mean reduction of 6.8 MHDs (95% CI: 5.2-8.3) from a baseline of 20.0 MHDs. Additionally, 26.1% of participants achieved >75% reduction in MHD at Month 6 (95% CI: 18.9%-35.0%).

Patients also reported an average increase of 6.3 additional "good days" per month (95% CI: 4.7-7.9) compared with baseline (10.0 days/month). Together these findings reflect notable reductions in migraine frequency and improvements in day-to-day functioning, suggesting a potential clinical benefit in considering eptinezumab earlier in the treatment pathway.[1]

Eptinezumab has been shown to be well tolerated across multiple clinical trials. The safety of eptinezumab has been evaluated in more than 2,000 adult patients with migraine who received at least one dose of eptinezumab. During the registrational trials, PROMISE-1 and PROMISE-2, the most common adverse reactions were nasopharyngitis and hypersensitivity.

The INFUSE study is part of Lundbeck's broader real-world evidence program in migraine. Lundbeck is committed to raising the bar within migraine care, working tirelessly to advance the understanding and management of migraine, a complex and progressive neurological disease that continues to impose a substantial burden on millions of people worldwide. Across our portfolio, we strive to develop innovative therapies, generate meaningful real-world evidence and support healthcare professionals in delivering effective, patient-centered care.

About migraine

Migraine is a complex and incapacitating neurological disease characterized by recurrent episodes of severe headaches typically accompanied by an array of symptoms, including nausea, vomiting, and sensitivity to light or sound. Not only is headache painful, but migraine also imposes both a social and financial burden. Migraine has a profound impact on patient functioning including relationships with family/friends, leisure activities, household production and worker productivity.

Migraine is one of the most prevalent neurological diseases for which medical treatment is sought and is considered the leading cause of disability for people under the age of 50 and the 2nd leading cause of disability worldwide.[8,9] Repeated migraine attacks, and often the constant fear of the next one, damage family life, social life and work life. Furthermore, increased use of acute headache medication may lead to central sensitization and decreased effectiveness of acute medication. This results in a vicious cycle of increased number of headache days requiring further increased amounts of acute headache medication. Without proper preventive migraine management, this process results in worsening and chronification of migraine.[10]

About the INFUSE study

The INFUSE study is a 12-month, prospective, observational study in the US, assessing real-world effectiveness of intravenous (IV) eptinezumab (100 mg or 300 mg) in adults with migraine who previously failed at least one preventive anti-CGRP. Data were collected digitally at baseline, Day 7, and Months 3, 6, 9 and 12 through participant-reported surveys. The primary

outcome was percent of patients with “much” or “very much” improved on the 7-point PGIC scale (“very much improved,” “much improved,” “minimally improved,” “no change,” “minimally worse,” “much worse,” or “very much worse”). Secondary outcomes included monthly headache days and ≥50% reduction in monthly headache days (MIDAS-derived) and number of patient-defined “good days”.[1]

Recruitment occurred via two eptinezumab Infusion Network partners, including ≥100 infusion centers, capturing outcomes during the course of routine clinical practice with minimal site involvement.

About Vyepti® (eptinezumab)

Eptinezumab is a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) which was intentionally designed for IV administration. The efficacy and safety of eptinezumab was evaluated in two Phase 3 clinical trials (PROMISE-1 in episodic migraine[11] and PROMISE-2 in chronic migraine),[12] where eptinezumab met its primary endpoint of decrease in monthly migraine days (MMDs) over weeks 1-12 in both episodic and chronic migraine.

Furthermore, the clinical trial program demonstrated a treatment benefit over placebo that was observed for both 100 mg and 300 mg doses of eptinezumab as early as Day 1 post-infusion. 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 (≥2% and at least 2% or greater than placebo) in the clinical trials for the preventive treatment of migraine were nasopharyngitis and hypersensitivity. In PROMISE-1 and PROMISE-2, 1.9% of patients treated with eptinezumab discontinued treatment due to adverse 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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