

Press release

Valby, 26 May 2026

Lundbeck receives marketing authorization for Vyepti® (eptinezumab) in South Korea for the preventive treatment of migraine

- Approval granted by South Korea's Ministry of Food and Drug Safety (MFDS)
- Eptinezumab is an anti-calcitonin gene-related peptide (CGRP) monoclonal antibody for the preventive treatment of migraine in adults
- Authorization supported by the Phase 3 SUNRISE trial conducted in a predominantly Asian population with chronic migraine
- Provides a new preventive treatment option for people living with migraine in Korea

Valby, Denmark, 26 May 2026 – H. Lundbeck A/S (Lundbeck) today announced that the Ministry of Food and Drug Safety (MFDS) of South Korea has granted marketing authorization for eptinezumab for use in adults with migraine.

Migraine is a progressive and debilitating neurological disease characterized by recurrent attacks of severe headache often accompanied by nausea, vomiting, and sensitivity to light and sound. Migraine affects one in seven people and is a leading cause of disability worldwide.¹

Approximately 11% of the population in Korea currently lives with migraine, a figure that may be underestimated.^{1,2} Despite its high prevalence, preventive treatments are often underutilized.³ Significant gaps remain in diagnosis, access to care, and effective treatment options.

“This approval marks an important milestone for people living with migraine in Korea, many of whom remain underserved by existing preventive options,” said Johan Luthman, EVP and Head of Research and Development at Lundbeck. “Expanding access to eptinezumab reflects our commitment to advancing brain health and delivering innovative therapies to patients across Asia who continue to experience a significant disease burden.”

Eptinezumab is a humanized monoclonal antibody that binds to CGRP and was intentionally designed for intravenous (IV) administration. The decision is based on results from the confirmatory Phase 3 trials PROMISE-1, PROMISE-2, DELIVER and SUNRISE. The latter trial, SUNRISE, was a randomized, placebo-controlled trial conducted in a predominantly Asian population with chronic migraine.

Eptinezumab was first approved by the U.S. Food and Drug Administration for the preventive treatment of migraine in adults, followed by additional approvals including in the European Union. It has since been launched in more than 30 markets worldwide.

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.^{4,5} 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.⁶

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 were evaluated in two Phase 3 clinical trials (PROMISE-1 in episodic migraine⁷ and PROMISE-2 in chronic migraine⁸), 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 ($\geq 2\%$ 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](#).

References:

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