Press release
Valby, 16 September, 2026

Lundbeck receives marketing authorization for Vyepti® (eptinezumab) in Japan for the prevention of migraine attacks

- Approval granted by Japan's Ministry of Health, Labour and Welfare (MHLW)
- Eptinezumab is the only intravenous (IV) CGRP-targeted preventive treatment approved for the prevention of migraine attacks in adults and launched in over 30 countries worldwide
- Authorization supported by the Phase III SUNRISE trial and the SUNSET long-term extension study in Japanese patients
- Building on 25 years of commitment to patients and brain health in Japan, the approval paves the way for Lundbeck's first launch in Japan as Marketing Authorization holder, enabling Lundbeck to operate independently on the Japanese market

Valby, Denmark, Wednesday 16 September 2026 – H. Lundbeck A/S (Lundbeck) today announced that the Ministry of Health, Labour and Welfare (MHLW) of Japan has granted marketing authorization for eptinezumab for the prevention of migraine attacks in adults, marking an important milestone for patients in Japan and for Lundbeck's continued growth in Asia.

Migraine is a debilitating neurological disease characterized by recurrent attacks of severe headache often accompanied by nausea, vomiting, and sensitivity to light and sound. In Japan, migraine affects an estimated 8.4%–11.0% of the population[1] and is the fourth leading cause of years lived with disability.[2] Beyond the physical symptoms, migraine significantly affects daily functioning, quality of life, work productivity and life course.[2] Migraine is estimated to cost the Japanese economy US$ 3 billion every year in lost productivity.[3]

"This approval represents a significant advancement for people living with migraine in Japan, where the disease continues to place a substantial burden on patients, families, and society," said Tarek Samad, EVP and Head of Research and Development at Lundbeck. "Eptinezumab is a differentiated IV CGRP-targeted therapy that offers adults living with migraine an important new treatment option, and we are proud to bring this innovative medicine to patients in Japan. This approval also marks an exciting new chapter for Lundbeck Japan as we prepare for our first independent launch, building on 25 years of commitment to patients and brain health in the country."

Eptinezumab is a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) and was developed for IV administration as a preventive treatment for migraine.

The Japanese marketing authorization is supported by the global clinical development program for eptinezumab, including the Phase III PROMISE-1, PROMISE-2 and DELIVER trials, together with data from the Phase III SUNRISE trial, which evaluated efficacy and safety in a predominantly Asian population with chronic migraine.[4] The application was further supported

by the Phase III SUNSET long-term extension study conducted specifically in Japanese patients to evaluate the long-term safety of eptinezumab.[2]

Eptinezumab was first approved by the U.S. Food and Drug Administration in 2020 for the preventive treatment of migraine in adults, followed by additional approvals including in the European Union and most recently South Korea. It has since been launched in more than 30 markets worldwide.

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 or sound. Not only is headache painful, but migraine also imposes both a social and financial burden. Migraine 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.[5,6] 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.[7]

About Vyepti® (eptinezumab)

Eptinezumab is a humanized mAb that binds to CGRP which was designed for IV administration. The efficacy and safety of eptinezumab were evaluated in two Phase III clinical trials, PROMISE-1 in episodic migraine[8] and PROMISE-2 in chronic migraine.[9] In both trials, eptinezumab met its primary endpoint of decrease in monthly migraine days (MMDs) over weeks 1-12.

The safety of eptinezumab has been evaluated in more than 5,000 adult patients with migraine who received at least one dose. Common adverse reactions in the placebo-controlled clinical trials for the preventive treatment of migraine 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. In Japan, eptinezumab is approved for the prevention of migraine attacks in adults. 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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