Press release
Valby, 14 November, 2025

Lundbeck files for marketing authorization across key Asian markets for Vyepti® (eptinezumab) for the preventive treatment of migraine

- Lundbeck's new drug application (NDA) for Vyepti® (eptinezumab) accepted by Japan's Ministry of Health, Labor and Welfare (MHLW), marking a significant step forward towards expanding access to the novel preventive migraine treatment for patients across Japan
- Similar marketing authorization applications also accepted in China and South Korea, supported by Phase 3 SUNRISE trial data confirming the preventive efficacy of eptinezumab in Asian patients with migraine
- The submissions represent a milestone in Lundbeck's Focused Innovator strategy, extending operational capabilities in Asia and demonstrating Lundbeck's leadership within the migraine space

Valby, Denmark, 14 November 2025 – H. Lundbeck A/S (Lundbeck) today announced the acceptance of its new drug application (NDA) for Vyepti® (eptinezumab) by the Ministry of Health, Labor and Welfare (MHLW) in Japan.

The submission reflects the culmination of a series of marketing authorization applications across Asia, including China and South Korea, with the goal of enabling access to eptinezumab for patients living with migraine, who are eligible for preventive therapy. If granted, this will signal the first marketing authorization for Lundbeck in Japan, and the first launch of a biologic by Lundbeck in China and South Korea.

"The acceptance of these regulatory applications signifies a critical milestone in Lundbeck's Asian development program for eptinezumab." said Johan Luthman, EVP and Head of Research and Development at Lundbeck. "Eptinezumab has the potential to fulfil a significant unmet need in Asia, where migraine preventive treatments remain underutilized. The eptinezumab global roll-out also paves the way for advancing additional migraine and neuro-rare programs to patients."

Despite the equally high prevalence of migraine in Asia as compared to Western countries, a significant unmet need remains in terms of appropriate diagnosis, management, and availability of migraine preventive treatments in East Asia.[1] In Japan it is reported that of individuals with migraine, 59.4% to 71.8% had never consulted a physician previously and similarly in Korea, this number is estimated to be around 75.6%.[1] In China, it is reported that only 13.8% of adults living with migraine will be clinically diagnosed.[2]

The Japanese submission is supported by a robust clinical data package, including results from the SUNRISE Phase 3 registrational trial, which was recently published in *Cephalalgia*.[3]

In the SUNRISE trial, eptinezumab was shown to be efficacious in the preventive treatment of migraine. The safety profile of eptinezumab was generally similar to placebo, previous trials,

and to the current labelled safety information in the United States prescribing information and EU Summary of Product Characteristics, with the most common treatment-emergent adverse events being COVID-19 and nasopharyngitis.

Lundbeck is working with regulatory authorities in China, South Korea, and Japan to make eptinezumab available to patients in Asia as quickly as possible. Already approved in more than 30 countries, this step highlights the company's commitment to improving brain health and addressing the urgent needs of people living with severe migraine.

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 the *SUNRISE* trial

SUNRISE (NCT04921384) was an interventional, multi-regional, multi-site, randomized, double-blind, placebo-controlled Phase 3 trial, to confirm the efficacy and safety of eptinezumab in a predominately Asian population with chronic migraine who are eligible for preventive treatment.[3] The study was conducted to support marketing authorization across Asia.

Chronic migraine was defined as migraine occurring on ≥8 days per month and headache occurring on >14 days. Participants were randomly allocated to one of three treatment groups: eptinezumab 300 mg, eptinezumab 100 mg, or placebo.

The double-blind, placebo-controlled treatment period was followed by an extension period where all participants received active treatment to further assess the safety and tolerability of eptinezumab. The total trial duration from the screening visit to the safety follow-up visit is approximately 36 weeks and includes a Screening Period (28-30 days), a Placebo-controlled Period (12 weeks), an Extension Period (12 weeks), and a Safety Follow-up Period (8 weeks).[3]

Participants in Japan completing the *SUNRISE* trial were offered to continue in the *SUNSET* trial (NCT05064371) which consisted of an open-label eptinezumab treatment of 60 weeks (five infusions), and a Safety Follow-up Period (8 weeks).[7]

The *SUNRISE* trial was initiated in May 2021 and was conducted in Mainland China, Georgia, Japan, Poland, Slovakia, South Korea, Spain and Taiwan. In the trial, 983 participants were randomized to receive eptinezumab 100 mg, 300 mg, or placebo by intravenous (IV) infusion.[3]

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[8]and PROMISE-2 in chronic migraine)[9], where eptinezumab met its primary endpoint of decrease in 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 approximately 5,700 employees in more than 50 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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