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Corporate Release

Vyepti® recommended for approval in the EU by CHMP for the preventive treatment of migraine in adults

- Subject to final approval by the European Commission, Vyepti® (eptinezumab) will be the first intravenous (IV) treatment approved for migraine prevention in Europe.

Valby, Denmark, November 12, 2021 - H. Lundbeck A/S (Lundbeck) announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion and recommended granting a marketing authorization to Vyepti® (eptinezumab) in the European Union (EU) for the preventive treatment of migraine in adults who have at least 4 migraine days per month. Subject to final approval by the European Commission, Vyepti will be the first and only approved IV treatment for migraine prevention in EU.

CHMP based its positive opinion on the efficacy and safety of Vyepti, which has been demonstrated in two phase III clinical trials (*PROMISE-1* in episodic migraine and *PROMISE-2* in chronic migraine). The clinical trial program demonstrated a reduction in monthly migraine days over placebo which was observed for both doses of Vyepti as early as day 1 post-infusion, and a sustained effect on patient-relevant outcomes was observed for up to 96 weeks.

The safety of Vyepti was evaluated in approximately 2,000 patients with migraine who received at least one dose of Vyepti. The most common adverse reactions (≥2 percent and at least 2 percent 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 percent of patients treated with Vyepti discontinued treatment due to adverse reactions.

Dr. Johan Luthman, EVP and Head of Research & Development in Lundbeck, said:
"*This positive CHMP opinion confirms our high expectations to Vyepti and brings Lundbeck one step closer to providing a much-needed new treatment option to millions of patients suffering from migraine in Europe. We look forward to the European Commission's decision and to potentially bringing this new treatment to address the high unmet need.*"

If approved by the European Commission, the marketing authorization will be valid in all EU Member States, Iceland, Norway, and Liechtenstein. The CHMP positive opinion is one of the final steps before the European Commission makes its decision on the Marketing Authorization Application. A final decision regarding the approval of Vyepti is expected from the European Commission in the coming months.

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 it is launched on the U.S. market. In

addition, Vyepti has been approved in Australia, Canada, Kuwait, Singapore and U.A.E and, is currently under review in 10 markets around the world.

About Vyepti®

Vyepti is a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) which was purposefully developed for IV administration. The efficacy and safety of Vyepti was demonstrated in two phase III clinical trials (*PROMISE-1* in episodic migraine and *PROMISE-2* in chronic migraine), where Vyepti met its primary endpoint of decrease in mean monthly migraine days (MMD) 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 doses of Vyepti as early as day 1 post-infusion. The safety of Vyepti was evaluated in 2,076 adult patients with migraine who received at least one dose of Vyepti. 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. 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 Vyepti discontinued treatment due to adverse reactions.

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 impose both a social and financial burden, affecting close to 50 million people in Europe. Repeated headache attacks, and often the constant fear of the next one, damage family life, social life and work life. Furthermore, frequent use of acute migraine treatments may leave patients experiencing, or at risk of developing, medication overuse headache.

Migraine has a profound impact on patient functioning including relationships with family/friends, leisure activities, household production and worker productivity. In Europe, migraine alone costs the economy EUR 18 billion annually according to the Cost of Brain Disorders in Europe paper and this is without the indirect cost associated with presenteeism (i.e. productivity losses due to reduced efficiency of persons who are not sufficiently ill to be absent from work). It is the second leading cause of years lived with disability (YLD) among all diseases and it is the top cause of YLD among patients aged 15 to 49 years, according to the Global Burden of Disease study.

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About H. Lundbeck A/S

H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) is a global pharmaceutical company specialized in brain diseases. For more than 70 years, we have been at the forefront of neuroscience research. We are tirelessly dedicated to restoring brain health, so every person can be their best.

Millions of people worldwide live with brain diseases, and far too many suffer due to inadequate treatment, discrimination, a reduced number of working days, early retirement, and other unnecessary consequences.

Our approximately 5,600 employees in more than 50 countries are engaged in the entire value chain throughout research, development, production, marketing, and sales. Our pipeline consists of several R&D programs, and our products are available in more than 100 countries. We have research centers in Denmark and the US, and our production facilities are located in Denmark, France, and Italy. Lundbeck generated revenue of DKK 17.7 billion in 2020 (EUR 2.4 billion; USD 2.7 billion).

For additional information, we encourage you to visit our corporate site www.lundbeck.com, and connect with us on Twitter at @Lundbeck and via LinkedIn.

Safe Harbor/Forward-Looking Statements

This corporate release contains forward-looking statements that provide our expectations or forecasts of future events such as new product introductions, product approvals and financial performance. Forward looking statements include, without limitation, any statement that may predict, forecast, indicate or imply future results, performance or achievements, and may contain words like "believe", "anticipate", "expect", "estimate", "intend", "plan", "project", "will be", "will continue", "will result", "could", "may", "might", or any variations of such words or other words with similar meanings. All statements other than statements of historical facts included in this presentation, including, without limitation, those regarding our financial position, business strategy, plans and objectives of management for future operations (including development plans and objectives relating to our products), are forward looking statements.

Such forward looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward looking statements. Factors that may affect future results include, among others, interest rate and currency exchange rate fluctuations, delay or failure of development projects, production or distribution problems, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Lundbeck's products, introduction of competing products, Lundbeck's ability to successfully market both new and existing products, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws and related interpretation thereof, and unexpected growth in costs and expenses.

The forward-looking statements in this document and oral presentations made on behalf of Lundbeck speak only as at the date of this presentation. Lundbeck does not undertake any obligation to update or revise forward-looking statements in this presentation or oral presentations made on behalf of Lundbeck, nor to confirm such statements to reflect subsequent events or circumstances after the date of the presentation or in relation to actual results, unless otherwise required by applicable law or applicable stock exchange regulations.