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Corporate Release

Lundbeck announces European Medicines Agency acceptance of marketing authorization application for eptinezumab for the prevention of migraine

Valby, Denmark, 22 December 2020 – Today, H. Lundbeck A/S (Lundbeck) announces acceptance of the filing for Vyepti™ (eptinezumab-jjmr) by the European Medicines Agency (EMA) for marketing authorization application (MAA) review. The filing seeks approval to introduce Vyepti to European citizens who live with migraine and are eligible for preventative therapy.

Vyepti is the most recent strategic brand added to Lundbeck's portfolio of treatments. As a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP), Vyepti prevents CGRP from binding to its receptor, and thereby prevents migraine attacks. Vyepti is set to be the first migraine preventive antibody that is given by intravenous (IV) administration which may provide benefits such as attaining immediate therapeutic drug levels in the blood stream and efficacy as early as on the day of infusion. As a 30-minute IV infusion administered every 12 weeks, Vyepti offers patients with migraine a preventive therapy with 4 treatments per year.

The acceptance of the Vyepti MAA for review marks the beginning of the formal review procedure for this potential new treatment by the EMA's Committee for Medicinal Products for Human Use (CHMP). Vyepti was approved by the U.S. Food and Drug Administration (FDA) for the preventive treatment of migraine in adults 22 February 2020 and was launched in April on the U.S. market. During 2020, Lundbeck has submitted an application for market authorization of Vyepti in several countries, including Canada, Australia, Switzerland, United Arab Emirates, Kuwait, the Philippines, Singapore, Indonesia, and Brazil. Development activities in other regions and countries around the world, including China and Japan, are in planning.

Dr. Johan Luthman, Executive Vice President, R&D at Lundbeck said:
"Lundbeck is pleased with the acceptance of Vyepti for regulatory review. Vyepti will address the need for powerful migraine prevention with an early onset of effect. There are many patients who are impacted by migraine and they deserve innovative and better treatment options – including migraine prevention that works in an effective, rapid, and sustained way. Therefore, we look forward to work closely with European health authorities to make Vyepti available as soon as possible."

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[1] and *PROMISE-2* in chronic migraine[2]), 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. 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.[3] Not only is headache painful, but migraine also impose both a social and financial burden, affecting close to 50 million people in Europe[4]. 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.

In Europe, migraine alone costs the economy EUR 18 billion annually according to the Cost of Brain Disorders in Europe paper[4] 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 YLD cause among patients aged 15 to 49 years, according to the Global Burden of Disease study.[5] Migraine has a profound impact on patients' lives, their relationships, as well as their ability to carry out activities of daily living.

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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. Every day, we strive for improved treatment and a better life for people living with brain diseases – we call this *Progress in Mind*.

Our approximately 5,800 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 billion in 2019 (EUR 2.3 billion; USD 2.6 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

The above information contains forward-looking statements that provide our expectations or forecasts of future events such as new product introductions, product approvals and financial performance.

Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations and it may cause any or all of our forward-looking statements here or in other publications to be wrong. Factors that may affect future results include interest rate and currency exchange rate fluctuations, delay or failure of development projects, production 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.

Certain assumptions made by Lundbeck are required by Danish Securities Law for full disclosure of material corporate information. Some assumptions, including assumptions relating to sales associated with product that is prescribed for unapproved uses, are made considering past performances of other similar drugs for similar disease states or past performance of the same drug in other regions where the product is currently marketed. It is important to note that although physicians may, as part of their freedom to practice medicine in the US, prescribe approved drugs for any use they deem appropriate, including unapproved uses, at Lundbeck, promotion of unapproved uses is strictly prohibited.

References

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