Corporate Releases

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FDA approves Lundbeck's Vyepti™ (eptinezumab-jjmr) – the first and only intravenous preventive treatment for migraine

- *In two clinical studies (PROMISE-1 in episodic migraine and PROMISE-2 in chronic migraine), Vyepti met its primary endpoint: decrease in mean monthly migraine days (MMD) over months 1-3.**[i]***
- *A treatment benefit over placebo was observed for both doses of Vyepti as early as day 1 post-infusion, and the percentage of patients experiencing a migraine was lower for Vyepti than with placebo for most of the first 7 days.*[i]
- *In both studies, Vyepti demonstrated a sustained reduction of MMD through the second dose (month 6).*[i]

Valby, Denmark, February 22, 2020 – H. Lundbeck A/S today announced that Vyepti™ (eptinezumab-jjmr) has been approved by the U.S. Food and Drug Administration (FDA) for the preventive treatment of migraine in adults and will be available in April 2020.[i] The recommended dose is 100 mg every 3 months; some patients may benefit from a dose of 300 mg.[i] Vyepti is the first FDA-approved intravenous (IV) treatment for migraine prevention.

Dr. Deborah Dunsire, President and CEO of Lundbeck, commented *"With the approval of Vyepti, I am pleased that we are now able to offer a new IV therapy that achieves the key treatment goal of preventing migraine over time while also delivering on the need for earlier onset of efficacy. The Vyepti clinical program is the first to demonstrate this early benefit."*

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).[i] 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, and the percentage of patients experiencing a migraine was lower for VYEPTI than with placebo for most of the first 7 days.[i] The safety of VYEPTI was evaluated in 2,076 patients with migraine who received at least one dose of Vyepti.[i] 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.[i] In PROMISE-1 and PROMISE-2, 1.9 percent of patients treated with Vyepti discontinued treatment due to adverse reactions.[i]

"The PROMISE-2 data showed that many patients can achieve reduction in migraine days of at least 75 percent and experience a sustained migraine improvement through 6 months, which is clinically meaningful to both physicians and patients," said Dr. Peter Goadsby, a professor of neurology at King's College, London and the University of California, San Francisco. "Vyepti is a valuable addition for the treatment of migraine, which can help reduce the burden of this serious disease."

About the *PROMISE* Clinical Trial Program

The efficacy of Vyepti™ (eptinezumab-jjmr) was evaluated as a preventive treatment of episodic and chronic migraine in two randomized, placebo-controlled studies, both with 6-month double-blind periods: one study in episodic (PROMISE-1; defined as 4-14 headache days per month, of which at least 4 were migraine days) and one study in patients with chronic migraine (PROMISE-2; defined as 15-26 headache days per month, of which at least 8 were migraine days).[i] In both studies, patients were randomized to receive placebo, Vyepti 100 mg, or Vyepti 300 mg.[i] The primary endpoint was the change from baseline in mean MMD over months 1-3.[i] Patients were allowed to use concurrent acute migraine or headache medications, including migraine-specific medications (i.e., triptans, ergotamine derivatives), during the trial.[i] Both studies excluded patients with a history of cardiovascular disease (hypertension, ischemic heart disease), neurological disease, and cerebrovascular disease.[i] In PROMISE-2, the study population included patients with a dual diagnosis of chronic migraine and medication overuse headache attributable to acute-medication overuse of triptans, ergotamine, or combination analgesics greater than 10 days per month.[i]

PROMISE-1: A total of 665 patients were randomized to receive placebo (N=222), 100 mg Vyepti (N=221), or 300 mg Vyepti (N=222) every 3 months for 12 months.[i]

- *Mean migraine frequency at baseline was approximately 8.6 migraine days per month and was similar across treatment groups.*[i]
- *Mean change from baseline in MMD with Vyepti compared with placebo months 1-3: -3.9 days for 100 mg (p=0.018), -4.3 days for 300 mg (p<0.001), and -3.2 days for placebo.*[i]
- *Percent responders with at least 50 percent reduction in MMD in months 1-3 compared with placebo: 49.8 percent for 100 mg (nominal statistical significance p=0.009), 56.3 percent for 300 mg (p<0.001), and 37.4 percent for placebo.*[i]
- *Percent responders with at least 75 percent reduction in MMD in months 1-3: 22.2 percent for 100 mg (p=NS*), 29.7 percent for 300 mg (p<0.001), and 16.2 percent for placebo.*[i]
- *Greater percentage of placebo-treated patients had migraine on most days during the first 7 days of treatment compared to Vyepti -treated patients.i*

*NS = Not statistically significant

PROMISE-2: A total of 1,072 patients were randomized to receive placebo (N=366), 100 mg Vyepti (N=356) or 300 mg Vyepti (N=350) every 3 months for 6 months.[i]

- *Mean migraine frequency at baseline was approximately 16.1 migraine days per month and was similar across treatment groups.*[i]
- *Mean change from baseline in MMD compared with placebo months 1-3: -7.7 days for 100 mg (p<0.001), -8.2 days for 300 mg (p<0.00 days for placebo.*[i]

- *Percent responders with at least 50 percent reduction in MMD in months 1-3 compared with placebo: 57.6 percent for 100 mg (p<0.001), 61.4 percent for 300 mg (p<0.001), and 39.3 percent for placebo.*[i]
- *Percent responders with at least 75 percent reduction in MMD in months 1-3: 26.7 percent for 100 mg (p<0.001), 33.1 percent for 300 mg (p<0.001), and 15.0 percent for placebo.*[i]
- *Greater percentage of placebo-treated patients had migraine on each individual day during the first 7 days of treatment compared to Vyepti-treated patients.i*

About VYEPTI™

Vyepti™ (eptinezumab-jjmr) is a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor.[i]

Lundbeck has submitted an application for market authorization of Vyepti in Canada and also plans to file in the European Union during 2020, followed by the submission of applications in other regions and countries around the world, including China and Japan.

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.[ii] It is estimated to affect approximately 39 million people in the U.S. and mora than 1.3 billion worldwide, and impacts three times as many women than men.[iii],[iv],[v] It is the second leading cause of years lived with disability (YLD) among all diseases, and is the top YLD cause among patients aged 15 to 49 years, according to the Global Burden of Disease study.[vi] Migraine has a profound impact on patients' lives, their relationships, as well as their ability to carry out activities of daily living.[v] More than 157 million work days are lost each year in the U.S. due to migraine. [iii]

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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.

An estimated 700 million people worldwide are living 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*.

Read more at www.lundbeck.com/global/about-us/progress-in-mind.

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.

[i] VYEPTI (eptinezumab) 2020 Full Prescribing Information.

[ii] Villalón CM. The role of CGRP in the pathophysiology of migraine and efficacy of CGRP receptor antagonists as acute antimigraine drugs. *Pharmacol Ther.* 2009;124(3):309-323

[iii] Migraine Research Foundation. Migraine Facts. Available at https://migraineresearchfoundation.org/about-migraine/migraine-facts/. Access January 12, 2020.

[iv] GBD 2017 Disease and Injury Incidence and Prevalence Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. The Lancet. 2018; 392: 1789–858

[v] Lipton RB, et al. Migraine prevalence, disease burden, and the need for preventative therapy. *Neurology.* 2007;68(5):343-349..

[vi] Steiner TJ, et al. Migraine is first cause of disability in under 50s: will health politicians now take notice? *J Headache Pain*. 2018;19(1):17.

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Attachment

- *FDA approves Lundbeck's Vyepti[™] (eptinezumab-jjmr) – the first and only intravenous preventive treatment for migraine*