Press release

Valby, 31 August 2020

Positive headline results from the Vyepti (eptinezumab-jjmr) RELIEF study

Initiating VYEPTI™ (eptinezumab-jjmr) migraine prevention during a migraine attack demonstrated positive results in the RELIEF study

H. Lundbeck A/S (Lundbeck) today announced headline results from the parallel group, double-blind, randomized, placebo-controlled *RELIEF* study[i] that assessed the efficacy and tolerability of Vyepti when initiated during a migraine attack in patients who are candidates for preventive therapy. The study met statistical significance on the co-primary endpoints, demonstrating that patients receiving a 100 mg Vyepti infusion during a migraine attack achieved earlier time to freedom from headache pain and absence of their most bothersome symptom compared to patients receiving placebo. The most bothersome symptom was the individual patient's choice between photophobia, phonophobia, and nausea.

The key secondary endpoints of proportion of patients with pain freedom and proportion of patient with absence of their most bothersome symptom at 2 hours after the start of infusion, also met statistical significance. All other secondary endpoints were also statistically significant.

Vyepti was well-tolerated as a preventive treatment when initiated during a migraine attack, consistent with the previous phase III studies with no new safety signals identified. 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.

Dr. Johan Luthman, Executive Vice President, R&D at Lundbeck said:
"We are excited to see yet another trial that reinforces the early-onset benefits of Vyepti. We continue to hear from migraine sufferers that early benefit of a preventive therapy is so important, which is why Lundbeck continues to focus our research on addressing earlier effect and other critical treatment goals that matter most to patients."

Lundbeck plans to share the full data at upcoming scientific meetings and will submit the study for publication in a peer-reviewed journal.

About the *RELIEF* study
In November 2019, Lundbeck initiated the *RELIEF* study assessing the efficacy and tolerability of Vyepti initiated during a migraine attack in patients who are candidates for preventive therapy, experiencing 4-15 migraine days per month. Subjects were randomized to receive a single dose of Vyepti or placebo in a 1:1 ratio (n=480) by a 30-minute IV infusion within 1 to 6 hours of migraine-attack onset. The total study duration was 4 to 12 weeks,

including up to an 8-week screening period, with clinic visits occurring on Screening, Day 0 (dosing day; patients were followed at the study site the first 4 hours after the infusion), and Week 4. Patients were allowed to utilize acute rescue medication at any time 2 hours after infusion.

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. Vyepti was developed for administration by IV infusion to deliver 100 percent of the medication into the blood stream.

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). Vyepti met its primary endpoint of decrease in mean monthly migraine days (MMD) over months 1-3 in both episodic and chronic migraine. The safety of Vyepti was evaluated in 2,076 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.

Administered as one 30-minute IV infusion every 3 months, Vyepti offers patients with migraine a preventive therapy with 4 infusions a year. The recommended dosage is 100 mg as an intravenous infusion every 3 months. Some patients may benefit from a dosage of 300 mg. Dosing should be based on the guidance in the Prescribing Information and Patient Information.

Vyepti was approved by the U.S. Food and Drug Administration (FDA) for the preventive treatment of migraine in adults in February 2020 and launched in April on the US market – only market where it is currently available. For more information, please visit www.VYEPTIHCP.com or see Prescribing Information and Patient Information.

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About Lundbeck
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 17.0 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.

[i] NCT04152083