Press release
Valby, 11 September, 2025

Lundbeck showcases new clinical migraine data, including long-term preventive effectiveness of Vyepti® (eptinezumab) in patients severely impacted by migraine

- Lundbeck demonstrates leadership and unwavering commitment to advancing migraine management and supporting patient outcomes with six presentations at the 2025 International Headache Congress (IHC), including three oral presentations on eptinezumab (Vypeti®) and Lu AG09222 (anti-PACAP mAb)
- New data from the open-label extension of the RESOLUTION trial and the primary results of the SUNSET extension trial will be presented for the first time at IHC[1,2]
- Patients treated with eptinezumab experienced sustained reductions in migraine symptom and burden, including long-term reduction in monthly migraine days (MMDs) and improvements in patient-reported outcomes[1,2]

Valby, Denmark, 11 September, 2025 – H. Lundbeck A/S (Lundbeck) is advancing leadership in migraine with a comprehensive collection of datasets to be presented at the 2025 International Headache Congress, taking place in São Paulo (Sept 10-13).[1-6] Among data presented, Lundbeck will announce the full results of the 12-week, open-label extension of the RESOLUTION trial investigating eptinezumab for the prevention of migraine in patients with chronic migraine and associated medication overuse headache (MOH) who also received standardized patient education.[1] In addition, new data from the SUNSET open-label extension trial in Japanese patients with chronic migraine will be shared with the scientific community for the first time.[2]

“Migraine is a chronic, disabling disease that disrupts lives and demands a comprehensive, long-term management approach,” said Johan Luthman, EVP, and Head of Research & Development at Lundbeck. “Patients deserve preventive treatments that not only deliver early relief but sustain their impact over time. The RESOLUTION and SUNSET trials show that patients who experience an early, clinically significant response with eptinezumab continue to maintain this response long-term. This offers renewed hope for those severely impacted by the burden of migraine.”

In the phase 4 RESOLUTION trial,[7] the early, clinically meaningful improvements in migraine symptom and burden observed during the initial placebo-controlled period were sustained during the open-label extension period. Around 50% of patients achieved a ≥50% reduction from baseline in monthly migraine days (MMDs) and achieved approximately nine days fewer MMDs at the end of the 12 week OLE, compared to baseline at the start of the RESOLUTION trial (baseline was 20.9 MMDs).[1]

Additionally, the primary results of the SUNSET trial will be presented at IHC. SUNSET was a 60-week open-label extension of the Asian registrational SUNRISE trial, designed to evaluate the

long-term safety, tolerability and efficacy of eptinezumab in a Japanese population with chronic migraine.[2]

In the trial the symptom reduction observed within the first 12 weeks of treatment with eptinezumab (SUNRISE trial) was maintained across the open-label period.[2] The proportion of participants with a ≥50% or ≥75% MMD reduction from baseline was sustained throughout the trial, with 35.7% of patients achieving a 50% reduction in MMD by week 49-60. A trend towards increasing ≥75% response rate was also observed across the 60-weeks extension period.[2]

Eptinezumab was well tolerated across both trials,[1,2] similar to previous trials in migraine prevention and to the current labelled safety information in the United States prescribing information and the EU Summary of Product Characteristics.

These data collectively underscore the long-term effectiveness, tolerability, and safety of eptinezumab in addressing the needs of patients severely impacted by migraine, and underscores Lundbeck's commitment to lifting the burden of migraine for patients globally.

Details of Lundbeck's scientific program at IHC:

Satellite symposium
Revolutionizing patient care through science: From neuropeptides to higher standards in migraine prevention. Speakers: Peter J. Goadsby, Gisela Terwindt and Stewart Tepper, Saturday 13 September: 13:00-14:30

Oral presentations
Efficacy and safety of eptinezumab in adults with chronic migraine and medication-overuse headache: 24-week results of the RESOLUTION trial. Presented by Henrik W Schytz. Saturday 13 September: 16:00-17:00[1]

Eptinezumab improved patient-reported disease burden and quality of life in a predominantly Asian population with chronic migraine: Secondary results from the SUNRISE trial. Presented by Patricia Pozo-Rosich. Saturday 13 September: 10:30-11:30[3]

Patient perspectives of migraine symptomology: Insights from exit interviews from the anti-PACAP antibody Phase 2 HOPE trial for migraine prevention. Presented by Richard Lipton. Saturday 13 September: 10:30–11:30.[4]

ePoster presentations
Eptinezumab reduced disease burden in chronic migraine and medication-overuse headache in patients also receiving patient education: Results from the placebo-controlled RESOLUTION trial. Tepper SJ, et al. Saturday 13th September[5]

Efficacy and safety of eptinezumab in chronic migraine: Randomized controlled trial in a predominantly Asian population. Yu S, et al. Friday 12th September[6]

Long-term tolerability and effectiveness of eptinezumab in Japanese adults with chronic migraine: The 60-week, open-label SUNSET trial. Takeshima T, et al. Saturday 13th September[2]

About migraine and medication-overuse headache (MOH)

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.[8]

Migraine 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.[9] As the most prevalent neurological disorder in people aged <50 years, migraine imposes both a social and financial burden. In Europe, migraine alone affects close to 50 million people costing the economy EUR 18 billion annually according to the Cost of Brain Disorders in Europe[10] study 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).

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 medications may lead to central sensitization and decreased effectiveness of the acute headache medication, resulting in a cycle of increased number of headache days requiring even further increased amounts of acute headache medication. Without proper migraine management, this process results in worsening migraine and may lead to the development of chronic migraine and MOH.[11] The secondary headache of MOH is a common complication among individuals with primary headache disorders like chronic migraine.

About the RESOLUTION trial

RESOLUTION was a phase 4, randomized, placebo-controlled trial designed to evaluate the efficacy of eptinezumab versus placebo in patients with chronic migraine and associated medication-overuse headache (MOH) who also received standardized patient education.[7] RESOLUTION included a 12-week double-blind, placebo-controlled period followed by a 12-week open-label extension. The participants in the RESOLUTION trial were mainly from European countries.

RESOLUTION is the first randomized controlled trial to assess the efficacy of an anti-CGRP treatment in combination with structured patient education in chronic migraine and MOH. The trial enrolled 608 participants with dual diagnoses of chronic migraine and MOH, and participants were randomly allocated to one of two treatment groups, brief educational intervention (BEI) and eptinezumab (100 mg; n = 305) or BEI and placebo (n = 303), in a 1:1 ratio. BEI involves a short screening followed by individual feedback on how and why acute migraine medication use should be reduced, and this approach to patient education has been shown to result in long-term medication reductions for patients with MOH.

At the end of Week 12, 584 participants continued in the 12-week, open-label extension, where all participants received eptinezumab 100 mg. Clinical efficacy endpoints included change from baseline in MMDs, ≥50% and ≥75% responder rate and change from baseline in monthly days with acute medication use. Key secondary endpoints included reductions in headache-related burden, migraine-related disability, work productivity loss, activity impairment, and the safety and tolerability of eptinezumab in this patient population.

About the SUNSET trial

The SUNSET trial (NCT05064371) was an extension of the phase 3, multiregional, randomized, double-blind, placebo-controlled SUNRISE trial (NCT04921384) conducted in adults (18–75 years) diagnosed with chronic migraine.[2] 159 Japanese participants who completed SUNRISE were enrolled and treated in SUNSET after completing 12-week, randomized, double-blind treatment with IV eptinezumab 100 mg, 300 mg, or placebo. SUNSET comprised a 60-week open-label treatment period (during which participants received IV eptinezumab every 12 weeks [5 doses total] and completed a daily electronic diary) and an 8-week safety follow-up period. All participants received eptinezumab 100 mg at baseline in SUNSET, participants who did not achieve ≥50% reduction from SUNRISE baseline in monthly migraine days (MMDs; SUNSET Weeks 1–12) had their dose increased to 300 mg at SUNSET Week 12 and onward.
The primary endpoints investigated long-term safety and tolerability, including treatment emergent adverse events (TEAEs). Secondary endpoints included change from baseline in the number of MMDs, ≥50% and ≥75% migraine responder rates (MRRs), and Patient Global Impression of Change (PGIC) score. Exploratory endpoints included change from baseline in the Migraine-specific Work Productivity and Activity Impairment (WPAI:M) questionnaire domain scores.

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 III clinical trials (PROMISE-1 in episodic migraine[12] and PROMISE-2 in chronic migraine[13]), 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 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.

References:

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