

## Press release

Valby, 13 April 2026

# Lundbeck to showcase new neurology data at the American Academy of Neurology Annual Meeting

- Seven abstracts represent data across migraine, childhood-onset epilepsy and multiple system atrophy (MSA), highlighting Lundbeck's biology-driven approach to developing treatments for serious brain diseases
- Oral presentation of new Phase 1 safety and tolerability data for bocunebart (Lu AG09222), an investigational anti-PACAP monoclonal antibody in migraine prevention
- Three VYEPTI® (eptinezumab) abstracts include clinical data and new real-world evidence in migraine
- Neuro-rare pipeline updates feature long-term data for bexicaserin in developmental and epileptic encephalopathies (DEEs), and clinical perspectives on disease progression in MSA

**Valby, Denmark, 13 April 2026** – H. Lundbeck A/S (Lundbeck) today announced that new data across its neurology portfolio will be presented at the American Academy of Neurology (AAN) Annual Meeting 2026, taking place April 18–22 in Chicago, U.S. The presentations span migraine, developmental and epileptic encephalopathies (DEEs) and multiple system atrophy (MSA), and underscore Lundbeck's focus on advancing brain disease treatments where there is significant unmet need.

“Neuroscience is reaching an inflection point. Progress in human genetics, biomarker validation, and the understanding of neuro-rare and migraine disease biology is opening new possibilities,” said Johan Luthman, EVP and Head of Research & Development at Lundbeck. “Our approach is to translate these insights into drug development programs that validate mechanisms early and focus on areas where patients still have few or no treatment options.”<sup>i</sup>

Among the highlights are new Phase 1 data on bocunebart, a potential first-in-class investigational monoclonal antibody that targets pituitary adenylate cyclase-activating polypeptide (PACAP), a pathway distinct from the calcitonin gene-related peptide (CGRP) mechanism targeted by current preventive migraine therapies. The analysis evaluates the safety and tolerability of bocunebart when administered alongside a gepant, a class of oral CGRP receptor antagonist commonly used in migraine management.

Lundbeck will also present data on eptinezumab, an intravenous anti-CGRP preventive treatment for migraine. These include a post-hoc analysis from DELIVER, a randomized Phase 3b trial investigating headache-free periods and patient-reported outcomes in individuals whose migraine had not responded to multiple prior preventive treatments. New interim findings from the ongoing 12-month INFUSE real-world study will report six-month outcomes, including data on migraine-related cognitive symptoms, in patients who had experienced failures with at least one prior anti-CGRP preventive treatment.

In rare childhood-onset epilepsy, Lundbeck will present primary 12-month results from the open-label extension of the Phase 1b/2a PACIFIC trial evaluating bexicaserin, an investigational selective 5-HT<sub>2C</sub> receptor superagonist being studied for the treatment of seizures in DEEs, including Dravet syndrome and Lennox-Gastaut syndrome.

Separately, findings will be presented from a Delphi consensus study in MSA, a rare neurodegenerative movement disorder with no currently approved treatment. The Delphi panel examined the appropriateness of expressing treatment effect as a percentage-wise slowing of clinical progression on the Unified Multiple System Atrophy Rating Scale (UMSARS), and the threshold for clinical meaningfulness.

Together, these data highlight Lundbeck's expanding neurology pipeline and its continued commitment to advancing treatments for serious brain diseases.

### Details of Lundbeck presentations at AAN 2026

| Therapeutic Area        | Presentation content   | Presentation Type | Reference                        |
|-------------------------|--|-------------------|----------------------------------|
| bocunebart (Lu AG09222) | Safety and Tolerability of Anti-PACAP Monoclonal Antibody Lu AG09222 when Co-administered with a Gepant in Participants with Migraine  | Oral Presentation | Session S37 005, 22 April, 12:03 |
| bocunebart (Lu AG09222) | Pharmacokinetics and Safety of the Anti-PACAP Monoclonal Antibody Lu AG09222, in Development for Migraine Prevention, in Three Phase I Trials  | Poster            | P10 15-015                       |
| VYEPTI® (eptinezumab)   | Real-World Effectiveness of Eptinezumab in Patients in Whom ≥1 Prior Anti-CGRP Preventive Treatment had Failed: 6-Month Results for an Ongoing Prospective Study                         | Poster            | P10 15-006                       |
| VYEPTI® (eptinezumab)   | Real-World Effect on Cognitive Symptoms After Eptinezumab Treatment in Patients in Whom ≥1 Prior Anti-CGRP Preventive Treatment had Failed: 6-Month Results for the Ongoing INFUSE Study | Poster            | P1 15-006                        |
| VYEPTI® (eptinezumab)   | Eptinezumab's Effect on Interictal Periods and Quality of Life in participants with Migraine for Whom 2–4 Prior Preventive Treatments had Failed   | Poster            | P10 15-001                       |

|             |   |        |            |
|-------------|---|--------|------------|
| Bexicaserin | Long-term Safety, Tolerability, and Efficacy of Bexicaserin for the Treatment of Seizures in Participants With Developmental and Epileptic Encephalopathies: Primary Results of the 12-Month Phase 1b/2a PACIFIC Trial Open-Label Extension | Poster | P11 10-004 |
| MSA         | Interpretation of Clinical Progression in Multiple System Atrophy Using Percentage-wise Slowing in the Unified Multiple System Atrophy Rating Scale (UMSARS) Score  | Poster | P10 16-002 |

## 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.<sup>ii</sup> Not only is migraine painful but also imposes both a social and financial burden. Migraine has a profound impact on patient functioning including relationships with family/friends, leisure activities, household production and work productivity.

Migraine is one of the most prevalent neurological diseases for which medical treatment is sought and is considered the leading cause of disability for people under the age of 50 and the 2nd leading cause of disability worldwide.<sup>iii,iv</sup> Repeated migraine attacks, and often the constant fear of the next one, damage family life, social life and work life. As migraine frequency and severity increase, attacks become harder to control, requiring patients to take more headache medication while experiencing less relief. This cycle contributes to a greater disease burden and, without appropriate preventive management, can lead to further worsening and chronification of migraine.<sup>v</sup>

## About Vyepti® (eptinezumab)

Eptinezumab is a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) which was purposefully developed for intravenous (IV) administration. The efficacy and safety of eptinezumab 100 mg and 300 mg was investigated in two Phase 3 clinical trials (*PROMISE-1* in episodic migraine<sup>vi</sup> and *PROMISE-2* in chronic migraine)<sup>vii</sup>, where eptinezumab 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 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 ( $\geq 2\%$  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 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.

## INDICATION

VYEPTI (eptinezumab-jjmr) is indicated for the preventive treatment of migraine in adults.

## IMPORTANT SAFETY INFORMATION CONTRAINDICATIONS

VYEPTI is contraindicated in patients with serious hypersensitivity to eptinezumab-jjmr or to any of the excipients. Reactions have included anaphylaxis and angioedema.

## WARNINGS AND PRECAUTIONS

**Hypersensitivity Reactions:** Hypersensitivity reactions, including angioedema, urticaria, facial flushing, dyspnea, and rash, have occurred with VYEPTI in clinical trials and in the postmarketing setting. Most hypersensitivity reactions occurred during infusion and were not serious, but often led to discontinuation or required treatment. Serious hypersensitivity reactions may occur. Cases of anaphylaxis have been reported in the postmarketing setting. If a hypersensitivity reaction occurs, consider discontinuing VYEPTI and institute appropriate therapy.

**Hypertension:** Development of hypertension and worsening of pre-existing hypertension have been reported following the use of CGRP antagonists, including VYEPTI, in the postmarketing setting. Some of the patients who developed new-onset hypertension had risk factors for hypertension. There were cases requiring initiation of pharmacological treatment for hypertension, and in some cases hospitalization. Hypertension may occur at any time during treatment, but was most frequently reported within 7 days of therapy initiation. The CGRP antagonist was discontinued in many of the reported cases.

Monitor patients treated with VYEPTI for new-onset hypertension or worsening of pre-existing hypertension, and consider whether discontinuation of VYEPTI is warranted if evaluation fails to establish an alternative etiology or blood pressure is inadequately controlled.

**Raynaud's Phenomenon:** Development of Raynaud's phenomenon and recurrence or worsening of pre-existing Raynaud's phenomenon have been reported in the postmarketing setting following the use of CGRP antagonists. In reported cases with monoclonal antibody

CGRP antagonists, symptom onset occurred a median of 71 days following dosing. Many of the cases reported serious outcomes, including hospitalizations and disability, generally related to debilitating pain. In most reported cases, discontinuation of the CGRP antagonist resulted in resolution of symptoms.

VYEPTI should be discontinued if signs or symptoms of Raynaud’s phenomenon develop, and patients should be evaluated by a healthcare provider if symptoms do not resolve. Patients with a history of Raynaud’s phenomenon should be monitored for, and informed about the possibility of, worsening or recurrence of signs and symptoms.

### **ADVERSE REACTIONS**

The most common adverse reactions ( $\geq 2\%$  and at least 2% or greater than placebo) in the clinical trials for the preventive treatment of migraine were nasopharyngitis and hypersensitivity.

VYEPTI was approved by the U.S. Food and Drug Administration (FDA) for the preventive treatment of migraine in adults in February 2020. For more information, please see Full [Prescribing Information](#) and [Patient Information](#) or visit [www.VYEPTIHCP.com](http://www.VYEPTIHCP.com).

### About the INFUSE study

The INFUSE study is an ongoing 12-month, prospective, observational study in the US, assessing real-world effectiveness of IV eptinezumab (100 mg or 300 mg) in adults with migraine who previously failed at least one preventive anti-CGRP. Data were collected digitally at baseline, Day 7, and Months 3, 6, 9 and 12 through participant-reported surveys. The primary outcome was percent of patients with “much” or “very much” improved on the 7-point PGIC scale (“very much improved,” “much improved,” “minimally improved,” “no change,” “minimally worse,” “much worse,” or “very much worse”). Secondary outcomes included monthly headache days and  $\geq 50\%$  reduction in monthly headache days (MIDAS-derived) and number of patient-defined “good days”.<sup>viii</sup>

### About the DELIVER trial

DELIVER (NCT04418765) is a Phase 3b, multicenter, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of eptinezumab in patients with chronic or episodic migraine. Chronic migraine was defined as migraine occurring on  $\geq 8$  days per month and headache occurring on  $>14$  days, and episodic migraine as migraine occurring on  $\geq 4$  days and headache occurring on  $\leq 14$  days. All patients had to have experienced failures of two to four prior preventive treatment classes (including: propranolol, metoprolol, topiramate, amitriptyline, flunarizine, valproate, divalproex, candesartan) or botulinum toxin A/B (if documented that botulinum toxin was used for chronic migraine), and at least one failure being due to inadequate efficacy. Patients who experienced failure on a previous treatment targeting the CGRP pathway were excluded from participation. Documented evidence of prior migraine treatment failures was supported by medical records or by physicians’ confirmation specific to each treatment in the past 10 years.

## About bocunebart

Bocunebart is an investigational monoclonal antibody (mAb) with a novel mechanism of action. It was engineered to bind to and inhibit the signaling of pituitary adenylate cyclase-activating polypeptide (PACAP), a neuropeptide implicated in migraine pathophysiology. This mechanism operates through a pathway distinct from that targeted by anti-calcitonin gene-related peptide (anti-CGRP) therapies.<sup>x</sup> Bocunebart, which met its primary endpoint in the Phase 2b PROCEED trial in February, represents a potential new treatment class and could provide an alternative option for the preventive treatment of migraine. Bocunebart is an investigational mAb, not approved by the US Food and Drug Administration (FDA) or any other regulatory agency, and the efficacy and safety of bocunebart have not been established.

## About DEEs

Developmental and Epileptic Encephalopathies (DEEs) are a group of rare neurodevelopmental disorders that typically manifest in early childhood.<sup>x</sup> These heterogeneous and severe epilepsy syndromes are characterized by refractory seizures and developmental stagnation or regression.<sup>x</sup> According to the International League Against Epilepsy (ILAE), DEEs currently encompass more than 10 syndromes, including Early Infantile DEE (EIDEE), Infantile Epileptic Spasms Syndrome (IESS), Dravet Syndrome, and Lennox-Gastaut Syndrome with various etiologies among those mainly genetic (e.g., CDKL5, STXBP1, KCNT1, SCN2A). The etiology is unknown in approximately 50% of cases of DEE.<sup>x</sup>

## About bexicaserin

Bexicaserin is an investigational, oral, centrally acting, highly selective superagonist of the 5-HT<sub>2C</sub> receptor.<sup>xi</sup> Bexicaserin is being evaluated for the treatment of seizures in participants with any type of DEE in a global Phase 3 clinical program (the DEEp Program). The FDA has granted Breakthrough Therapy designation for bexicaserin for the treatment of seizures associated with DEEs for patients two years of age and older. Bexicaserin has also recently been granted Breakthrough Therapy Designation in China for the treatment of seizures associated with DEEs.

Bexicaserin is an investigational compound, not approved by the US Food and Drug Administration (FDA) or any other regulatory agency, and the efficacy and safety of bexicaserin have not yet been established.

## About multiple system atrophy

MSA is a rapidly progressing rare condition that causes damage to nerve cells in the brain. In a person with MSA, an abnormal build-up of the protein  $\alpha$ -synuclein is thought to be responsible for damaging the areas of the brain that control balance, movement, and the body's normal functions.<sup>i</sup> MSA is seriously debilitating and places a high disease burden on patients and their care partners. There is currently no cure for MSA and no available treatment to slow its clinical progression.<sup>xii</sup>

Symptoms of MSA usually start between 55 and 60 years of age, and the typical time to death is 8.6 years after symptom onset.<sup>xiii</sup> Although there are many different possible symptoms of MSA, not everyone who is affected will experience all of them. The symptoms of MSA are wide-ranging and may include muscle control problems, similar to those of Parkinson's disease.<sup>xiii</sup> Many different functions of the body can be affected, and symptoms can include urinary incontinence, dizziness when standing, balance and gait issues, and falls. MSA is accompanied by reduced capacity to live independently, and death is often due to respiratory problems.

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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 more than 5,000 employees in more than 20 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](http://www.lundbeck.com) and connect with us via [LinkedIn](#).

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