Press release
Valby, Denmark, 4 June, 2026

Lundbeck presents positive Phase IIb data for bocunebart (Lu AG09222; anti-PACAP mAb) in migraine prevention at the AHS congress

- The intravenous part of the Phase IIb clinical dose-finding trial PROCEED met its primary endpoint, with bocunebart demonstrating a statistically significant reduction in monthly migraine days versus placebo over Weeks 1–12 in patients with one to four prior preventive treatment failures
- Bocunebart was generally well tolerated, with no new safety signals identified
- The totality of the presented clinical data from the bocunebart Phase I-IIb program strengthens the evidence for PACAP pathway inhibition as a novel therapeutic approach for people severely impacted by migraine

Valby, Denmark, Thursday 4 June 2026 – Lundbeck today announced the first presentation of primary data from the Phase IIb PROCEED trial evaluating bocunebart (Lu AG09222), an investigational monoclonal antibody targeting pituitary adenylate cyclase-activating polypeptide (PACAP). The data presented at the American Headache Society (AHS) Congress in Orlando, Florida, USA (4-7 June) support the potential of bocunebart as a preventive treatment in patients with one to four prior preventive migraine treatment failures, with particularly notable treatment effect in those with chronic migraine.

Bocunebart is designed to bind to and inhibit PACAP, a neuropeptide implicated in migraine pathophysiology through pathways distinct from calcitonin gene-related peptide (CGRP). This differentiated mechanism positions bocunebart as a potential alternative treatment option for patients who do not achieve adequate benefit from currently available preventive therapies.

“I am encouraged by the positive results from the PROCEED trial. Despite advances in migraine management, a substantial proportion of patients still do not achieve adequate disease control with currently available therapies. The clinical evidence to date highlights the potential of bocunebart as a new therapeutic approach for migraine prevention and offers hope to patients living with this debilitating condition”, said the coordinating investigator of the trial and presenting author, Dr. Jessica Ailani, certified headache specialist, Washington DC.

In the intravenous (IV) dosing part of the PROCEED trial, bocunebart met the primary endpoint, demonstrating a statistically significant reduction from baseline in monthly migraine days (MMDs) over Weeks 1–12 compared with placebo. Patients treated with bocunebart experienced a mean reduction of -4.24 monthly migraine days versus -2.86 days with placebo, corresponding to a treatment difference of -1.38 days (p=0.0178).

In pooled data across the Phase II program of severe, chronic migraine patients, bocunebart showed a more pronounced effect with a mean reduction of -5.94 MMDs versus -3.63 MMDs with placebo, corresponding to a treatment difference of -2.31 days (p<0.001) in patients that had experienced prior preventive treatment failures.

Bocunebart was generally well tolerated, with no new safety signals identified during the treatment period. Across the Phase II program, the most commonly reported treatment-emergent adverse event (≥5%) for bocunebart was nasopharyngitis.

“Today’s data mark an important milestone in our efforts to bring forward innovative treatments for people living with migraine, particularly those who continue to experience substantial disease burden despite currently available therapies” said Johan Luthman, EVP and Head of Research and Development at Lundbeck. “The PROCEED results strengthen our confidence in targeting the PACAP pathway and support continued clinical development of bocunebart.”

In addition, Lundbeck presents Phase I clinical data evaluating the safety and tolerability of bocunebart when co-administered with ubrogepant in participants with migraine. Together with previously presented data on co-administration with triptans, these findings further support the safety profile of bocunebart when used alongside commonly prescribed acute migraine therapies.

Based on the positive PROCEED trial, Lundbeck is advancing preparations for further clinical development of bocunebart in migraine prevention. Lundbeck will host a conference call and live webcast for investors and analysts on Friday, June 5, 2026, at 15:00 CET (09:00 a.m. ET) to discuss the announcement. The webcast can be accessed through the Investor Relations section of Lundbecks’s website at www.lundbeck.com. A replay will be available shortly after the conclusion of the event.

About Lundbeck’s bocunebart scientific presentations at the AHS congress

Targeting PACAP in migraine prevention: Early outcomes from the PROCEED phase IIb trial of bocunebart (Lu AG09222)
Poster presentation: Jessica Ailani
Date: Thursday, June 4, 2026
Time: 6:00 pm – 7:30 pm EDT

Safety and Tolerability of Anti-PACAP Monoclonal Antibody Lu AG09222 when Co-administered with Ubrogepant in Participants with Migraine.
Poster presentation: Amaal Starling
Date: Thursday, June 4, 2026
Time: 6:00 pm – 7:30 pm EDT

About the PROCEED migraine trial

The PROCEED trial assessed the efficacy, safety, and tolerability of bocunebart versus placebo when administered once monthly for three months. The Phase IIb trial was designed to establish the optimal dose and route of administration (subcutaneous and intravenous) of bocunebart. A predefined interim analysis of the subcutaneous part of the PROCEED trial demonstrated futility and triggered enrolment into the intravenous (IV) part of the trial. In the IV part of PROCEED a total of 429 patients from 14 countries (Bulgaria, Czechia, Denmark, France, Georgia, Germany, Hungary, Lithuania, Japan, Poland, Romania, Slovakia, Spain, and the United States) were treated. The primary efficacy endpoint was defined as the difference between bocunebart and placebo in mean change from baseline in the number of monthly migraine days over Weeks 1 to 12.

The target population for this trial included patients diagnosed with migraine according to the International Classification of Headache Disorders, Third Edition (ICHD-3),[1] who had experienced treatment failure with one to four different preventive migraine medications within the past 10 years.

About the HOPE migraine trial

The HOPE trial was an interventional, multi-national, multi-site, randomized, double-blind, parallel-group, placebo-controlled Phase IIa trial designed to assess the safety, tolerability and efficacy of a single IV infusion of bocunebart for the prevention of migraine in patients that had failed prior treatments. The trial consisted of a 4-week double-blind treatment period with a follow-up period for 8 weeks. The primary endpoint was the change from baseline in the number of monthly migraine days over weeks 1 to 4, compared to placebo. Secondary endpoints were ≥50% reduction from baseline in MMDs (Weeks 1 to 4) and change from baseline in the number of monthly headache days (Weeks 1 to 4), compared to placebo.

The target population for this trial was defined as patients diagnosed with migraine as outlined in the International Classification of Headache Disorders Third Edition (ICHD-3) with unsuccessful prior preventive treatments A total of 237 patients, recruited from specialist settings, were randomly allocated via a randomization system to one of three treatment groups: two doses of bocunebart or placebo.

About bocunebart

Bocunebart is an investigational monoclonal antibody (mAb) with a novel mechanism of action. It is designed to bind to and inhibit the signalling 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. Bocunebart represents a potential new treatment class in migraine prevention and may provide an alternative option for people living with migraine who continue to be severely affected by the condition.

Bocunebart is an investigational drug that is not approved for marketing by any regulatory authority worldwide, and the efficacy and safety of bocunebart have not been established.

About migraine

Migraine is a complex and disabling neurological disease characterized by recurrent attacks of severe headache typically accompanied by an array of symptoms, including nausea, vomiting, and sensitivity to light or sound.[1]

Migraine is among the most prevalent neurological diseases worldwide and remains the leading cause of disability for people under the age of 50 and the 2nd leading cause of disability.[2] The disease has a profound impact on daily functioning, including relationships, social participation, household responsibilities, and work productivity. As migraine frequency and severity increase, attacks become more difficult to control, contributing to greater disease burden and can progress to chronic migraine in the absence of appropriate preventive management.[3]

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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 and connect with us via LinkedIn.

References:

1. Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3rd Edition. Cephalalgia, 2018. 38(1): p. 1-211
2. Burch, R.C., D.C. Buse, and R.B. Lipton, Migraine: epidemiology, burden, and comorbidity. Neurol Clin, 2019. 37(4): p. 631-649
3. Lipton RB, Buse DC, Nahas SJ, Tietjen GE, Martin VT, Löf E, Brevig T, Cady R, Diener HC. Risk factors for migraine disease progression: a narrative review for a patient-centered approach. J Neurol. 2023 Dec;270(12):5692-5710. doi: 10.1007/s00415-023-11880-2. Epub 2023 Aug 24. PMID: 37615752; PMCID: PMC10632231