

CORPORATE RELEASE

Valby, Denmark, February 12, 2026

Lundbeck announces positive phase IIb top-line results with bocunebart (Lu AG09222; anti-PACAP mAb) in migraine prevention

- The intravenous (IV) part of the phase IIb dose-finding PROCEED trial of bocunebart (Lu AG09222) met its primary endpoint in migraine prevention, demonstrating a statistically significant difference to placebo in the change from baseline in the number of monthly migraine days (MMDs) over weeks 1 to 12 in a population that experienced past treatment failures.
- The results demonstrate the potential of bocunebart in severe migraine.
- Additional analyses will be done to better understand the dose-response relationship across the investigated doses.
- Based on this positive outcome, Lundbeck will approach regulatory authorities to discuss the results and phase III design options.

Valby, Denmark, February 12, 2026 - H. Lundbeck A/S (Lundbeck) announced positive results, meeting its primary endpoint, in the multiple IV dosing part of PROCEED, an adaptive phase IIb dose-finding and route of administration trial of bocunebart (Lu AG09222). The trial investigated bocunebart as a potential treatment for the prevention of migraine in a population that experienced 1-4 previous preventive treatment failures in the past 10 years (NCT06323928). Bocunebart was generally well tolerated, and no new safety signals were detected during the PROCEED trial.

These data build on findings from the previously successful HOPE phase IIa trial evaluating single IV administration of bocunebart.

"I am encouraged by the positive results from the PROCEED trial. The efficacy demonstrated in this trial represent a promising advancement in the treatment of migraine, offering hope to many patients suffering from this debilitating condition," said the coordinating investigator of the trial, Dr. Jessica Ailani, certified headache specialist, Washington DC.

Dr. Johan Luthman, EVP and Head of Research & Development in Lundbeck, said:

"This milestone is a testament to our commitment to advancing brain health with innovative treatments that focus on addressing significant unmet medical needs. These data underline Lundbeck's ambition to deliver the first PACAP targeting option in migraine prevention. With its novel mechanism of action, it has the potential to become an important addition to the migraine treatment paradigm, furthering Lundbeck's mission to improve outcomes for people living with severe migraine."

Lundbeck is grateful to all the participants with migraine, their families, and the investigators who participated in the trial and contributed greatly to this research.

The trial results are planned to be presented at an upcoming conference and submitted for scientific publication at a later date.

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 PROCEED trial aimed to establish the optimal dose and route of administration, subcutaneous and IV, of bocunebart. In the IV part of PROCEED a total of 431 patients from 14 countries (Bulgaria, Czechia, Denmark, France, Georgia, Germany, Hungary, Lithuania, Japan, Poland, Romania, Slovakia, Spain, and the United States) were randomized. The primary efficacy endpoint was defined as the difference between bocunebart and placebo in the mean change from baseline in the number of monthly migraine days over weeks 1 to 12.

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)ⁱ and with treatment failure of 1-4 different preventive migraine medications in the past 10 years.

About bocunebart

Bocunebart is an investigational monoclonal antibody (mAb) with a novel mechanism of action. It is 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) therapiesⁱⁱ. Bocunebart represents a potential new treatment class and could provide an alternative option for migraine prevention, offering hope to individuals severely affected by the condition.

Bocunebart 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 bocunebart have not been established.

About migraine

Migraine is a complex and incapacitating neurological disease characterized by recurrent episodes of moderate to severe, pulsating headaches typically accompanied by an array of symptoms, including nausea, vomiting, and sensitivity to light and soundⁱⁱⁱ. As the most prevalent neurological disorder in people aged <50 years, migraine imposes both a social and financial burden, affecting around 135 million people in the G7 countries plus China. Repeated migraine attacks, and often the constant fear of the next one, damage family life, social life and work life^{iv}.

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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.

Safe Harbor/Forward-Looking Statements

This corporate release contains forward-looking statements that provide our expectations or forecasts of future events such as new product introductions, product approvals and financial performance. Forward looking statements include, without limitation, any statement that may predict, forecast, indicate or imply future results, performance or achievements, and may contain words like "believe", "anticipate", "expect", "estimate", "intend", "plan", "project", "will be", "will continue", "will result", "could", "may", "might", or any variations of such words or other words with similar meanings. All statements other than statements of historical facts included in this presentation, including, without limitation, those regarding our financial position, business strategy, plans and

objectives of management for future operations (including development plans and objectives relating to our products), are forward looking statements.

Such forward looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward looking statements. Factors that may affect future results include, among others, interest rate and currency exchange rate fluctuations, delay or failure of development projects, production or distribution 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.

The forward-looking statements in this document and oral presentations made on behalf of Lundbeck speak only as at the date of this document. Lundbeck does not undertake any obligation to update or revise forward-looking statements in this presentation or oral presentations made on behalf of Lundbeck, nor to confirm such statements to reflect subsequent events or circumstances after the date of the presentation or in relation to actual results, unless otherwise required by applicable law or applicable stock exchange regulations.

ⁱ Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3rd Edition. Cephalalgia, 2018. 38(1): p. 1-211.

ⁱⁱ Al-Karagholi, M.A.M., Zhuang, Z.A., Beich, S. et al. PACAP38-induced migraine attacks are independent of CGRP signaling: a randomized controlled trial. J Headache Pain 26, 79 (2025).

ⁱⁱⁱ Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3rd Edition. Cephalalgia, 2018. 38(1): p. 1-211

^{iv} Burch, R.C., D.C. Buse, and R.B. Lipton, Migraine: epidemiology, burden, and comorbidity. Neurol Clin, 2019. 37(4): p. 631-649.