Press release

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# Lundbeck's potential first-in-class therapy for migraine prevention enters advanced clinical stage

**PROCEED, a clinical phase IIb dose-finding trial will assess the efficacy and safety of subcutaneously administered Lu AG09222 in migraine prevention.**

H. Lundbeck A/S (Lundbeck) announced the advancement of the clinical development of Lu AG09222 for migraine prevention with the initiation of PROCEED, a randomized, double-blind, phase IIb, dose-finding trial to assess efficacy and safety of multiple subcutaneously administered doses.

The PROCEED trial builds on the positive results of the HOPE phase IIa Proof-of-Concept trial demonstrating efficacy of intravenously administered Lu AG09222 in migraine prevention.

Lu AG09222 is an investigational monoclonal antibody (mAb) with an innovative mode of action. It is designed to bind and inhibit signaling mediated by pituitary adenylate cyclase-activating polypeptide (PACAP); a neuropeptide that is implicated in migraine pathophysiology.

Lu AG09222 may offer a potential treatment option in a new treatment class for people with migraine. It is directed at a migraine pathway that is distinct from the pathway targeted by the recently introduced anti-calcitonin gene-related peptide (anti-CGRP) treatment approach.

"Initiation of this phase IIb trial of Lu AG09222 further progresses our neurology pipeline and emphasizes Lundbeck's commitment to people living with migraine and headache-related disorders. The diverse nature of the disease highlights the need for exploring novel therapeutic approaches that can address unmet needs. Lu AG09222 has a good chance of being first-in-class with this interesting mechanism," said Johan Luthman, EVP, and Head of Research & Development at Lundbeck.

## About the PROCEED migraine trial

PROCEED is an interventional, randomized, double-blind, parallel-group, placebo-controlled, dose-finding phase IIb trial that will be conducted in Europe, Japan and the US. It assesses four different doses of Lu AG09222 versus placebo, administered subcutaneously once monthly for three months. The trial is intended to establish the optimal dose for future global pivotal trials designed to confirm the efficacy and safety of Lu AG09222 as a migraine preventive treatment. PROCEED is planned to enroll approximately 498 patients and will assess the efficacy, safety and tolerability of Lu AG09222. The target population for this trial is 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 2-4 different preventive migraine medications in the past 10 years. Study completion is expected in H2 2025.

## About Lu AG09222

Lundbeck is developing Lu AG09222, an investigational monoclonal antibody (mAb) designed to bind and inhibit pituitary adenylate cyclase-activating polypeptide (PACAP)[ii]. PACAP has emerged as a neuropeptide implicated in the pathophysiology of migraine and represents a novel target in migraine.

Completed clinical trials with Lu AG09222 have demonstrated Proof-of-Mechanism showing that Lu AG09222 can halt PACAP38-triggered vasodilation and headaches and Proof-of-Concept of efficacy in migraine prevention. The HOPE phase IIa Proof-of-Concept trial met the primary endpoint; the difference from placebo in mean change in MMDs from baseline over weeks 1-4 was significant versus placebo. Lu AG09222 was generally well tolerated in these trials.

Together, these data confirm a role of PACAP in migraine pathophysiology and support Lu AG09222 as a potential first-in-class preventive treatment of migraine and possibly other pain related indications.

## 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 sound[iii]. 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].

## Contacts


Thomas Mikkel Mortensen
Media Relations Lead, Corp. Communication
THMR@lundbeck.com
+45 30 83 30 24

Palle Holm Olesen
Vice President, Investor Relations
PALO@lundbeck.com
+45 30 83 24 26

Sophia Nørskov Bech
Senior Manager, Investor Relations
SONQ@lundbeck.com
+45 30 83 24 60


## About H. Lundbeck A/S

Lundbeck is a biopharmaceutical company focused exclusively on neuroscience, with more than 70 years of experience in improving the lives of people with neurological and psychiatric diseases.

As a focused innovator, we strive for our research and development programs to tackle some of the most complex challenges. We develop transformative medicines targeting people for whom there are few, if any, treatment options.

Our goal is to create long term value and make a positive contribution to people and societies, everywhere we operate. We are committed to fighting stigma and discrimination, and we act to improve health equity for the people we serve and the communities we are part of.

For additional information, we encourage you to visit our corporate site www.lundbeck.com and connect with us via LinkedIn.

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[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] Moldovan Loomis, C., et al., Pharmacologic Characterization of ALD1910, a Potent Humanized Monoclonal Antibody against the Pituitary Adenylate Cyclase-Activating Peptide. J Pharmacol Exp Ther, 2019. 369(1): p. 26-36

[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.