Press Release
Valby, Denmark, 31 March 2025

Following a planned interim analysis in the PROCEED trial Lundbeck expands the dose finding to intravenous administration of Lu AG09222 in migraine prevention

- PROCEED is an adaptive Phase IIb trial with Lu AG09222, an investigational mAb intended to block signaling by pituitary adenylate cyclase-activating polypeptide (PACAP), a neuropeptide that is believed to contribute to migraine.
- The PROCEED trial is designed to explore different doses and routes of administration of Lu AG09222 in patients with migraine for whom one to four previous preventive treatments had failed to provide a benefit.
- Following the recruitment of approximately 75% of the patients in a subcutaneously (SC) administration dose-finding part of PROCEED, a pre-specified interim analysis is triggering an expansion of the trial, by the initiation of an intravenously (IV) dose-finding part.

H. Lundbeck A/S (Lundbeck) is announcing reaching 75% recruitment target in the SC dose-finding part (Part A) in the phase IIb *PROCEED* trial, that explores dose and route of administration of the anti-PACAP mAb Lu AG09222.

Based on a pre-specified interim outcome assessment following SC route of administration, Lundbeck will now expand *PROCEED* to obtain further IV dose-response information on Lu AG09222 in migraine prevention, building further on findings from the previously successful *HOPE* Phase IIa trial evaluating IV administration of Lu AG09222. Lundbeck can leverage its already established IV clinical infusion infrastructure for migraine prevention.

Despite the advancements in migraine treatment, there remains a significant unmet need in migraine management, with an estimated 2.5 to 3.0 million patients in the G7 countries who are inadequately treated with currently approved treatments. Lu AG09222 has, through its binding to PACAP, the potential to become a first in class migraine preventive treatment.

The PROCEED trial is expected to be completed in the first half of 2026 with planned pivotal phase III initiation in second half of 2026.

About the PROCEED trial

Lundbeck initiated the *PROCEED* Phase IIb trial March 2024. PROCEED is an interventional, randomized, double-blind, parallel-group, placebo-controlled, dose-finding phase IIb trial that is

conducted in Europe, Japan, and the U.S. 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)[ii] and with treatment failure of 1-4 different preventive migraine medications in the past 10 years. The PROCEED trial assesses the efficacy, safety, and tolerability of Lu AG09222 versus placebo, when administered once monthly for three months. The PROCEED trial is intending to establish the optimal route of administration and dose of Lu AG09222, through an adaptive design consisting of a Part A, in which Lu AG09222 is administered SC and an optional Part B, in which Lu AG09222 is given IV. The initiation of the Part B, IV dose-response exploration in *PROCEED* is based on a pre-specified futility interim analysis of Part A, when about 75% of the patients have been randomized.

About Lu AG09222

Lundbeck is developing Lu AG09222, an investigational monoclonal antibody (mAb) with an innovative mode of action, designed to bind and inhibit pituitary adenylate cyclase-activating polypeptide (PACAP)[i]. PACAP has emerged as a neuropeptide implicated in the pathophysiology of migraine and represents a novel target in migraine. Lu AG09222 represents a potential new therapeutic option, targeting a pathway in migraine that is distinct from the CGRP pathway.

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[ii]. 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[iii].

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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 5,500 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.

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[i] 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

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

[iii] Burch, R.C., D.C. Buse, and R.B. Lipton, Migraine: epidemiology, burden, and comorbidity. Neurol Clin, 2019. 37(4): p. 631-649.