



Corporate Release

Lundbeck announces positive phase II Proof of Concept results with Lu AG09222 in migraine prevention

- The HOPE trial met its primary endpoint in migraine prevention, demonstrating that patients treated with Lu AG09222 had a statistically significantly greater reduction in number of monthly migraine days (MMDs) from baseline to weeks 1 to 4 of treatment compared to placebo.
- Lu AG09222 was well tolerated

Valby, Denmark, April 19, 2023 - H. Lundbeck A/S (Lundbeck) announced positive results of the HOPE trial, a clinical proof of concept trial of Lu AG09222 as a potential treatment for the prevention of migraine (NCT05133323). The primary analysis concluded that there was a statistically significant difference ($p=0.01$) between Lu AG09222 and placebo in the mean change from baseline in the number of monthly migraine days over weeks 1 to 4.

The phase IIa double-blind, placebo-controlled trial of Lu AG09222 was designed to assess the efficacy, safety, and tolerability of a single intravenous infusion of Lu AG09222. The trial consisted of a 4-week, double-blind treatment period, and an 8-week follow-up period after the last dose. A total of 237 patients were randomized in the trial.

Lu AG09222 is an investigational monoclonal antibody (mAb) that 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 represents a potential new therapeutic option, targeting a pathway in migraine that is distinct from the recently available calcitonin gene-related peptide (CGRP) migraine treatment drug class.

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

"This is the first investigational compound targeting PACAP that has demonstrated efficacy in a migraine prevention trial. Based on this positive outcome, Lu AG09222 will progress into further development. With its novel mechanism of action, it has the potential to become an important addition to Lundbeck's migraine portfolio, augmenting our efforts in helping patients with migraine and potentially other pain related indications globally."

Full trial results are not yet available. Further prespecified and exploratory analyses of the data set will be conducted to determine the potential of Lu AG09222 in the prevention of migraine in adult patients.

Lu AG09222 was generally well tolerated.



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

The trial results are planned to be submitted for scientific publication at a later date.

Lundbeck will discuss the further clinical development plan with regulatory authorities.

About the phase II 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 intravenous infusion of Lu AG09222 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 $\geq 50\%$ 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 Lu AG09222 or placebo.

About Lu AG09222

Lundbeck is developing Lu AG09222, an investigational monoclonal antibody (mAb) 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 recently available calcitonin gene-related peptide (CGRP) migraine treatment drug class.

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 soundⁱⁱ. 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 lifeⁱⁱⁱ.

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About H. Lundbeck A/S

Lundbeck is a global pharmaceutical company specialized in brain diseases. For more than 70 years, we have been at the forefront of neuroscience research. We are tirelessly dedicated to restoring brain health, so every person can be their best. We are committed to fighting stigma and discrimination against people living with brain diseases and advocating for broader social acceptance of people with brain health conditions. Our research programs tackle some of the most complex challenges in neuroscience, and our pipeline is focused on bringing forward transformative treatments for brain diseases for which there are few, if any therapeutic options.

For additional information, we encourage you to visit our corporate site www.lundbeck.com and connect with us on Instagram ([h_lundbeck](https://www.instagram.com/h_lundbeck)), Twitter at [@Lundbeck](https://twitter.com/Lundbeck) and via LinkedIn.

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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.

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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.