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Corporate Release

# Lundbeck announces supportive phase II results with Lu AF82422 in the treatment of Multiple System Atrophy from the AMULET trial

- *Signals of efficacy were observed across clinical and biomarker endpoints in a small exploratory proof-of-concept trial of 61 Multiple System Atrophy (MSA) patients (40 on Lu AF82422 versus 21 on placebo)*
- *Although the AMULET trial did not show statistical significance on its primary endpoint in slowing the rate of progression of MSA as measured by UMSARS Total Score, a trend of a slowing MSA progression was observed in the group exposed to Lu AF82422*

**Valby, Denmark, January 31st 2024** - H. Lundbeck A/S (Lundbeck) announced results of the AMULET trial, a phase II, randomized, double-blind, placebo-controlled clinical trial of Lu AF82422 as a potential treatment for patients with Multiple System Atrophy (MSA) (NCT05104476).

Signals of efficacy were observed across other clinical and biomarker endpoints, the analysis concluded that there was no statistically significant difference between Lu AF82422 and placebo in the longitudinal changes from baseline in the UMSARS Part I and Part II Total Score after 48 to 72 weeks of treatment.

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 AF82422 in the treatment of MSA, and to define the path of Lu AF82422 development.

Lu AF82422 was generally well tolerated.

*The outcome of the trial is encouraging despite not reaching statistical significance. We will now finalize the analysis of the data and plan the next step for progressing the Lu AF82422 MSA program in dialogue with health authorities. We are looking forward to further understand the potential of this program for the benefit of MSA patients. Lundbeck is grateful to all the patients, investigators and caregivers who participated in the trial and contributed to this research*. said Johan Luthman, EVP and Head of R&D, Lundbeck.

The trial results are planned to be submitted at scientific conferences and publications at a later date.

**Conference Call and Webcast**
Lundbeck will host a conference call and webcast at 15:00 CET on 31st January. To register for the call, please use this link: **Conference call**

The conference call will be webcast live. Please use this link to access the webcast: **Webcast**

The webcast can also be accessed through Lundbeck's website at www.lundbeck.com in the "Investors" section. To ensure a timely connection, it is recommended that participants register at least 15 minutes prior to the scheduled webcast. A replay of the webcast will be available on the company's website after the event.

## About the AMULET study

The AMULET study was a phase II, randomized, double-blind, placebo-controlled clinical trial of Lu AF82422 as a potential treatment for patients with MSA. A total of N=61 MSA patients were randomized 2:1 to either Lu AF82422 or placebo and treated between 48 to 72 weeks, followed by an ongoing 48 weeks open-label extension period offering all participants to receive treatment with Lu AF82422.

The primary objective was to evaluate the efficacy of Lu AF82422 on disease progression in patients with MSA, aiming at showing a slowing in disease progression in the active treatment arm compared to placebo on a 5% significance level evaluated 1-sided as well as safety and tolerability. The secondary objectives included evaluation of Lu AF82422 on patient's functioning, disease severity and other aspects of MSA.

Lu AF82422 was delivered as an intravenous infusion every four weeks.

## About Lu AF82422

Lu AF82422 is a human monoclonal antibody (mAb) that recognizes and binds to all major forms of extracellular α-syn and thereby prevents uptake and inhibits seeding of aggregation. Lu AF82422 has an active Fc region, which may increase immune-mediated clearance of α-syn/mAb complexes through microglia mediated uptake. Lu AF82422 is being developed by Lundbeck under a joint research and licensing agreement between Lundbeck and Genmab A/S

## About Multiple System Atrophy

MSA is a rapidly progressing rare condition of the nervous system that causes damage to nerve cells in the brain. MSA is seriously debilitating and places a high disease burden on patients. Symptoms of MSA usually start between 55 and 60 years of age and the patients typically live for 6 to 9 years after symptom onset[1].

In a person with MSA, an abnormal build-up of the protein alpha-synuclein is thought to be responsible for damaging areas of the brain that control balance, movement, and the body's normal functions[1].

The symptoms of MSA are wide-ranging and include muscle control problems, similar to those of Parkinson's disease[1]. Many different functions of the body can be affected, and symptoms including urinary incontinence, frequent falling, and unintelligible speech occur within 3 years of disease onset and are accompanied by reduced capacity to live independently. Death is often due to respiratory problems. Although there are many different possible symptoms of MSA, not everyone who is affected will experience all of them. There is currently no cure for MSA and no available treatment to slow its progression[1].

References:

1 – NHS : Multiple system atrophy - NHS (www.nhs.uk)

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## 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.

### 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.**

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