

CORPORATE RELEASE

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Lundbeck announces last patient randomized ahead-of-schedule in Phase 3 MASCOT trial

- MASCOT is a first-of-its-kind, Phase 3 trial supporting the development of amlenetug, an investigational therapy for people living with multiple system atrophy (MSA), a rare and fatal neurodegenerative disorder¹
- Amlenetug is a novel monoclonal antibody that demonstrated promising results in a Phase 2 trial, suggesting potential to slow disease progression in MSA
- Early completion of randomization underscores the significant unmet need in MSA, strong collaboration with patient and investigator communities, and Lundbeck's robust research and development capabilities
- Headline results anticipated in Q3 2027, with expected launch in Q1 2029

Valby, Denmark, March 9, 2026 – H. Lundbeck A/S (Lundbeck) today announced that the last patient has been randomized in MASCOT (NCT06706622), a global Phase 3 clinical trial evaluating amlenetug in people with multiple system atrophy (MSA), a rapidly progressing and fatal neurodegenerative disease for which no approved treatments currently exist.¹

Randomization was completed earlier than anticipated, underscoring the broad engagement across the global MSA community and Lundbeck's commitment to bringing innovation to patients with high unmet medical need.

The multicenter MASCOT trial is currently ongoing across North America, Europe, Asia, and Australia to evaluate the potential of amlenetug to slow the clinical disease progression of MSA.

"Completing randomization of a global Phase 3 trial in MSA is a significant achievement for the field," said Professor Prof. Günter Höglinger, Lead Investigator of the MASCOT trial. "Advancing the development of a potential treatment for this underserved disease addresses a critical unmet need for people living with MSA."

Amlenetug is designed to target the α -synuclein protein in the brain and inhibit its spread to nearby brain cells. By addressing a key underlying cause of MSA, amlenetug holds the potential to become a first-in-class therapy for this rare disorder.

"With no currently available treatments to slow the clinical progression of MSA, the urgency for innovation is exceptionally high," said Johan Luthman, Executive Vice President and Head of Research and Development at Lundbeck. "Successfully randomizing the last patient into the trial sets us on a strong trajectory to hopefully bring a much-needed treatment to people living with this devastating disease."

Amlenetug has received Orphan Drug Designation in the EU, Japan, and the U.S., as well as Fast Track designation in the U.S. and SAKIGAKE designation in Japan.

With randomization now complete, the MASCOT trial will continue as planned, with participants progressing through the double-blind treatment period followed by the optional open-label extension.

Amlenetug is an investigational compound that is not approved for marketing by any regulatory authority worldwide, and the efficacy and safety of amlenetug have not been established.

About Multiple System Atrophy

MSA is a rapidly progressing rare condition that causes damage to nerve cells in the brain. In a person with MSA, an abnormal build-up of the protein α -synuclein is thought to be responsible for damaging the areas of the brain that control balance, movement, and the body's normal functions.¹ MSA is seriously debilitating and places a high disease burden on patients. There is currently no cure for MSA and no available treatment to slow its clinical progression.²

Symptoms of MSA usually start between 55 and 60 years of age, and the typical time to death is 8.6 years after symptom onset.² Although there are many different possible symptoms of MSA, not everyone who is affected will experience all of them. The symptoms of MSA are wide-ranging and include muscle control problems, similar to those of Parkinson's disease.² 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. MSA is accompanied by reduced capacity to live independently, and death is often due to respiratory problems.

About amlenetug

Amlenetug is a human monoclonal antibody (mAb) that recognizes and binds to all major forms of extracellular α -synuclein and thereby intended to prevent uptake and inhibit seeding of aggregation. Amlenetug is being developed by Lundbeck under a joint research and licensing agreement between Lundbeck and Genmab A/S.

About the MASCOT trial

MASCOT (NCT06706622) is a Phase 3 interventional, randomized, double-blind, parallel-group, placebo-controlled, optional open-label extension trial that will be conducted in North America, Europe, Asia and Australia.³

The trial comprises 2 parts: A double-blind period where participants are randomized to receive either high or low doses of amlenetug, or placebo for 72 weeks, followed by an open-label extension period where all participants enrolled in the trial are offered treatment with amlenetug. The aim of the trial is to evaluate the efficacy, safety, and tolerability of amlenetug in patients with MSA. Amlenetug is delivered as an intravenous infusion every four weeks.

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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 corporate release, 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,

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The forward-looking statements in this document and in 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 corporate release or oral presentations made on behalf of Lundbeck, nor to confirm such statements to reflect subsequent events or circumstances after the date of the release, presentation or in relation to actual results, unless otherwise required by applicable law or applicable stock exchange regulations.

References:

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