Press release

Valby, 5 March 2024

Lundbeck presents encouraging results from the Lu AF82422 trial for Multiple System Atrophy at the international AD/PD 2024 conference on neurodegenerative disorders

The AMULET trial strengthens the case for Lundbeck's Lu AF82422, as initial clinical data suggests that the anti-alpha-synuclein monoclonal antibody (mAb) has a potential to slow clinical progression.

H. Lundbeck A/S (Lundbeck) announces clinical data from the AMULET phase II, double-blind, randomized trial of Lu AF82422 in Multiple System Atrophy (MSA) at the International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders (AD/PD 2024) on March 8, 2024, in Lisbon, Portugal. The presentation will start at 4:35 PM CET.

Lu AF82422 is a human monoclonal antibody (mAb) that recognizes and binds to all major forms of extracellular alpha-synuclein and thereby is believed to prevent uptake and inhibit seeding of aggregation.

Lu AF82422 may offer a potential treatment option by targeting the underlying disease pathology of MSA and aiming at slowing clinical progression.

Based on the encouraging AMULET trial outcomes, Lundbeck plans to initiate a phase III study, following further dialogue with health authorities.

“We are excited to be presenting data that advances a possible option for addressing a significant unmet need. We are looking forward to further understanding the potential of this program for the benefit of MSA patients,” said Johan Luthman, EVP, and Head of Research & Development at Lundbeck.

Scientific presentation from Lundbeck at AD/PD 2024

Supportive results from the AMULET phase 2, double-blind, randomized trial of Lu AF82422 in multiple system atrophy.

- AMULET (NCT05104476) was a double-blind, placebo-controlled trial investigating the safety and efficacy of monthly IV infusions with Lu AF82422 in patients with MSA.
- 61 participants were treated with Lu AF82422 (n=40) or placebo (n=21).
- The primary endpoint showed a non-statistically significant 19% slowing of clinical progression measured by UMSARS Total Score (UMSARS Part I + Part II) in the Lu AF82422 group vs placebo.
- The slope analysis of mUMSARS, UMSARS part I and part II showed a consistent slowing in clinical progression of 27%, 22% and 17%, respectively.

- A trend towards smaller regional MRI volumetric reduction in the Lu AF82422 group vs placebo was also observed.
- Lu AF82422 was generally well tolerated.

Lundbeck is grateful to all the trial participants, and the investigators who contributed greatly to this research.

About the AMULET trial

AMULET trial 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 clinical progression in patients with MSA, aiming at showing a slowing in clinical 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 is believed to prevent uptake and inhibit 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)

H. Lundbeck A/S (Lundbeck)

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.