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Corporate Release

Lundbeck presents new efficacy and safety data analyses for desmoteplase in patients with acute ischaemic stroke

- *In the per-protocol population desmoteplase was associated with better functional outcome compared to placebo as assessed by the modified Rankin Scale*
- *In additional data analyses it is suggested that magnetic resonance imaging (MRI) is more sensitive than computed tomography (CT) scanning for identifying appropriate patients likely to benefit from desmoteplase*
- *In the study the safety profile of desmoteplase was similar to placebo*
- *Lundbeck will discuss potential next steps with regulatory authorities*
- *Acute ischaemic stroke is a medical emergency and one of the leading causes of death and long-term disability worldwide; no medical treatment is approved in the extended time window of up to 9 hours after onset of symptoms*

Valby, Denmark, 25 October 2014 - H. Lundbeck A/S (Lundbeck) today presented additional results from the *Desmoteplase in Acute Ischaemic Stroke* (DIAS-3) study[i] in patients with acute ischaemic stroke treated in the time window of 3 to 9 hours after onset of symptoms. As communicated on 27 June 2014 there was no significant difference in the primary endpoint, the functional outcome measured by modified Rankin scale (mRS), between patients treated with desmoteplase or placebo at day 90 in the Full Analysis Set (FAS). However, among patients in the per-protocol population treatment with desmoteplase was associated with better functional outcome compared to placebo. The clinical meaning of the observed benefit of desmoteplase is that patients will experience less disability with regard to activities of daily living, even when treated in the extended time-window of up to nine hours.

These findings were presented as a late-breaking session at the 9th World Stroke Congress (WSC) in Istanbul, Turkey on 25 October 2014.

The assessment of early ischaemic tissue injury and of intracranial cerebral artery obstruction with either computerized tomography (CT) or magnetic resonance imaging (MRI) can be challenging. As a result, several patients were enrolled in the DIAS-3 study who did not meet key imaging inclusion criteria as defined in the study protocol. In the per-protocol population, i.e. among patients who fulfilled pre-specified enrolment criteria, desmoteplase was associated with better functional outcome compared to placebo as measured by mRS at day 90. The scale measures disability or dependence in activities of daily living.

The additional data analyses suggest that MRI is more sensitive than CT for detecting ischaemic injury in patients presenting in the extended time-window. In the pre-specified analysis of patients with <25 ml

of early ischaemic injury, treatment with desmoteplase was associated with better functional outcome in those patients who were identified with MRI, however not in those who were selected with CT.

"*Today most stroke patients are evaluated with a CT scan which can show bleeding in the brain, but may be insufficient for determining the extent of ischaemic injury of the brain tissue*", said Anders Gersel Pedersen, EVP and head of R&D in Lundbeck. "*Modern MRI technology is a superior method for detecting early ischaemic damage and can help clinicians to determine which patients are likely to benefit from treatment.*"

As previously announced the safety profile of desmoteplase was comparable to that of placebo. The symptomatic intracerebral haemorrhage (sICH) rates in all treated patients were 2.5% (desmoteplase) and 2.1% (placebo) after completion of the study follow-up period to day 90. Further, mortality rates and other safety outcomes were similar in both treatment groups.

Median time from symptom onset to treatment was 7.0 hours.

Considering that no other medication is available for treatment within the nine hour treatment window, the demonstrated effect in the per-protocol population, and the safety and tolerability profile seen in the clinical trials with desmoteplase, further development will be evaluated with advice from key clinical and regulatory experts during the next few months. This evaluation will not be concluded in 2014, but if the outcome is negative a write-down of DKK 330 million will be recognised in the R&D cost line in 2015.

About the DIAS-3 study

DIAS-3 was a multi-centre, randomised, double-blind, placebo-controlled study in 479 patients from 18 countries in Europe and Asia. Patients with symptoms of stroke and a treatable ischaemic stroke pathology (proximal cerebral vessel occlusion/high-grade stenosis without signs of extensive infarction, intracranial haemorrhage or sub-acute infarction), as assessed by magnetic resonance imaging (MRI) or computerised tomography (CT) scanning were randomised to receive either desmoteplase (90 µg/kg) or placebo within three to nine hours of symptom onset.

About desmoteplase

Desmoteplase, a fibrin-dependent plasminogen activator, is a genetically engineered version of a clot-dissolving protein found in the saliva of the vampire bat Desmodus rotundus. It has received fast-track designation from the U.S. Food and Drug Administration (FDA) for the treatment of acute ischaemic stroke.

About acute ischaemic stroke (AIS)

Stroke is a medical emergency bringing an enormous burden. The annual incidence rate of stroke in the US varies between 150-200 cases per 100,000 people, corresponding to 795,000 cases. For major 5 European countries (France, Germany, Italy, Spain, UK) the incidence rate is estimated at 110-220 cases per 100,000 people a year, resulting in approximately 700,000 cases annually. In Japan, the reported incidence rate is twice as high as that in Europe and the US, i.e. 410 cases per 100,000 people a year, leading to approximately 350,000 cases annually. The overall incidence rate in the less developed countries, traditionally lower than that in the developed countries, has surpassed the latter and is still rising.

Stroke is the third leading cause of disability and the second largest cause of mortality globally.

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About Lundbeck

H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) is a global pharmaceutical company specialized in brain diseases. For more than 50 years, we have been at the forefront of research within neuroscience. Our key areas of focus are alcohol dependence, Alzheimer's disease, bipolar disorder, depression/anxiety, epilepsy, Huntington's disease, Parkinson's disease, schizophrenia, stroke and symptomatic neurogenic orthostatic hypotension (NOH).

An estimated 700 million people worldwide are living with brain disease and far too many suffer due to inadequate treatment, discrimination, a reduced number of working days, early retirement and other unnecessary consequences. Every day, we strive for improved treatment and a better life for people living with brain disease – we call this Progress in Mind.

Read more at www.lundbeck.com/global/about-us/progress-in-mind.

Our approximately 6,000 employees in 57 countries are engaged in the entire value chain throughout research, development, production, marketing and sales. Our pipeline consists of several late-stage development programmes and our products are available in more 100 countries. We have research centres in China, Denmark and the United States and production facilities in China, Denmark, France and Italy. Lundbeck generated revenue of approximately DKK15.3 billion in 2013 (EUR2.1 billion; USD2.7 billion).

Lundbeck's shares are listed on the stock exchange in Copenhagen under the symbol "LUN". Lundbeck has a sponsored Level 1 ADR program listed in the US (OTC) under the symbol "HLUYY". For additional information, we encourage you to visit our corporate site www.lundbeck.com.

Safe Harbor/Forward-Looking Statements

The above information contains forward-looking statements that provide our expectations or forecasts of future events such as new product introductions, product approvals and financial performance.

Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations and it may cause any or all of our forward-looking statements here or in other publications to be wrong. Factors that may affect future results include interest rate and currency exchange rate fluctuations, delay or failure of development projects, production problems, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Lundbeck's products, introduction of competing products, Lundbeck's ability to successfully market both new and existing products, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws and related interpretation thereof, and unexpected growth in costs and expenses.

Certain assumptions made by Lundbeck are required by Danish Securities Law for full disclosure of material corporate information. Some assumptions, including assumptions relating to sales associated with product that is prescribed for unapproved uses, are made taking into account past performances of other similar drugs for similar disease states or past performance of the same drug in other regions where the product is currently marketed. It is important to note that although physicians may, as part of their freedom to practice medicine in the US, prescribe approved drugs for any use they deem appropriate, including unapproved uses, at Lundbeck, promotion of unapproved uses is strictly prohibited.

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[i] ClinicalTrials.gov identifier: NCT00790920