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Corporate Release

Lundbeck provides update on the development program for desmoteplase

- *The first of two phase III clinical studies (DIAS-3) in patients with acute ischaemic stroke treated in the time-window 3-9 hours after stroke onset did not meet the primary endpoint*
- *When analysing only the patients fulfilling all protocol requirements (per protocol population) desmoteplase showed an effect relative to placebo*
- *The study demonstrated an excellent tolerability profile of desmoteplase*
- *As a consequence of the results the further development plan is under consideration*

Valby, Denmark, 27 June 2014 - H. Lundbeck A/S (Lundbeck) today announced the initial headline conclusions from DIAS-3, the first of two phase III clinical trials of desmoteplase for the treatment of adult patients with acute ischaemic stroke.

The study did not meet the primary endpoint, i.e. the proportion of patients with a favourable outcome of modified Rankin Scale (mRS) score 0-2 at Day 90 was not statistically different between patients treated with desmoteplase (51.3%) and patients in the placebo control group (49.8%).

The DIAS-3 study confirmed the favourable safety profile of desmoteplase by providing excellent safety and tolerability data. Desmoteplase was well tolerated with adverse events at placebo level. In particular, the mortality was equal between treatment groups and the rate of symptomatic intracranial haemorrhage (the most serious adverse event associated with the current available thrombolytic treatment) after desmoteplase treatment was also comparable to placebo.

"It is obviously disappointing for us, treating physicians and patients that desmoteplase did s not met the primary endpoint in the study, also considering that desmoteplase seems safe and showed an effect in the predefined per protocol population", said Anders Gersel Pedersen, EVP and head of R&D in Lundbeck and continues *"We will now consult with clinical and regulatory experts about the future of the desmoteplase project".*

The DIAS-3 study protocol defined the target population as patients with symptoms of stroke and treatable ischaemic stroke pathology (proximal cerebral vessel occlusion/high-grade stenosis without signs of extensive infarction, intracranial haemorrhage or sub-acute infarction). Analysing only the patients fulfilling the protocol requirements (per protocol population) a favourable effect of desmoteplase was observed relative to placebo measured by mRS. This result is in line with the hypothesis based on the earlier post-hoc analysis of DIAS-2 on the target patient population[i].

As a consequence of the failure to meet the primary outcome, but considering the efficacy signal in the per protocol population and the excellent safety and tolerability, further development will be evaluated

with advice from key clinical and regulatory experts during the next few months in order to evaluate if a path forward is feasible.

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.

Further results of the study will be presented at a scientific congress and published in a scientific journal.

Financial guidance

The content of this release will have no influence on the Lundbeck Group's financial guidance on revenue or core EBIT for 2014 which were provided on 23 June 2014. The status of the desmoteplase program is depending on the internal and external evaluation during the next few months. If the outcome of this evaluation is negative a write-down of DKK 330 million will be recognised in the R&D cost line as communicated earlier this year.

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 U.S., 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 biggest cause of disability and the second biggest 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 development and distribution of pioneering treatments continues to make a difference to people living with brain diseases. Our key areas of focus are alcohol dependence, Alzheimer's disease, depression/ anxiety, epilepsy, Huntington's disease, Parkinson's disease, schizophrenia and stroke.

Our approximately 6,000 employees in 57 countries are engaged in the entire value chain throughout research, development, production, marketing and sales, and are committed to improving the quality of life of people living with brain diseases. Our pipeline consists of several late-stage development programs and our products are available in more 100 countries. We have research centers in China, Denmark and the United States, and production facilities in China, Denmark, France, Italy and Mexico. Lundbeck generated revenue of DKK 15.3 billion in 2013 (EUR 2.0 billion; USD 2.7 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.

[i] Jochen B. Fiebach, MD; Yasir Al-Rawi, MBChB; Max Wintermark, MD; Anthony J. Furlan, MD; Howard A. Rowley, MD; Annika Lindste´n, BSc; Jamal Smyej, BSc; Paul Eng, PhD; Steven Warach, MD; Salvador Pedraza, MD: "Vascular Occlusion Enables Selecting Acute Ischemic Stroke Patients for Treatment With Desmoteplase"; Stroke, 2012; 43:1561-1566