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Corporate Release

Lundbeck starts clinical phase III program with Lu AF35700 in patients with treatment resistant schizophrenia

- *A clinical phase III multi-national study with approximately 1,000 patients has been initiated*
- *Lu AF35700 has a novel pharmacological profile with predominant D_1 vs. D_2 dopamine receptor occupancy combined with high 5-HT_6 receptor occupancy. The program follows demonstration of good safety profile in phase I trials in both healthy subjects and patients with schizophrenia*
- *Lu AF35700 may become the first new pharmacotherapy in decades for patients with treatment resistant schizophrenia (TRS)*
- *Patients with treatment resistant schizophrenia account for a significant part of the total health care costs associated with schizophrenia*[i]

Valby, Denmark, 11 March 2016 - H. Lundbeck A/S (Lundbeck) today announced that the investigational compound Lu AF35700, a novel antipsychotic, is entering clinical phase III program.

Lundbeck is initiating the phase III program which is currently planned to consist of two pivotal trials. Two doses of Lu AF35700 (10 and 20 mg) will be tested in patients with treatment resistant schizophrenia. The primary endpoint is change from baseline to study week 10 in Positive and Negative Syndrome Scale (PANSS) total score. Additional endpoints include Clinical Global Impression – Severity of Illness (CGI-S) score and Personal and Social Performance Scale (PSP).

The first study is planned to enroll approximately 1,000 patients in approximately 15 countries including the U.S. and Canada and is expected to last around three years.

Lu AF35700 has been granted Fast Track designation in treatment resistant schizophrenia by FDA.

"*The initiation of the study demonstrates our global commitment to the development of Lu AF35700 and to the investigation of difficult-to-treat brain diseases such as treatment resistant schizophrenia*" says Anders Gersel Pedersen, EVP and Head of R&D at Lundbeck. "*We are excited about advancing Lu AF35700 with its unique pharmacology into an area of highest unmet medical need. Today there is only one therapy approved for patients with treatment resistant schizophrenia, and its use is severely limited by its problematic safety profile*"

The pivotal clinical program with Lu AF35700 now commencing will be a global program and consists of several studies involving more than 2,000 patients.

About Lu AF35700

Lu AF35700 has a novel pharmacological profile with predominant D_1 vs. D_2 dopamine receptor occupancy, and a high occupancy of 5-HT_{2A} and 5-HT_6 serotonin receptors.

The relatively low dopamine D_2 receptor occupancy of Lu AF35700 is expected to result in reduced burden of adverse events, such as EPS, prolactin elevation, dysphoria/anhedonia, and depressed mood. In completed safety trials, Lu AF35700 was generally well tolerated with a beneficial safety profile.

In November 2015, FDA granted Fast Track designation for Lu AF35700 – a first important step to ensure a potential expedited approval of the compound.

About treatment resistant schizophrenia (TRS)

Schizophrenia is a chronic, severe mental health disorder that often become disabling. Around 30% of patients with schizophrenia fail to respond to pharmacological treatment and are considered treatment resistant[ii]. These patients account for a significant part of the health care costs associated with schizophrenia including hospitalization and other health resource utilization.

Clozapine is the only medication with proven efficacy in treatment resistant schizophrenia, but is often not well tolerated, and requires regular monitoring as it is associated with a number of serious safety issues, which limits its use.

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About H. Lundbeck A/S

H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) is a global pharmaceutical company specialized in psychiatric and neurological disorders. For more than 70 years, we have been at the forefront of research within neuroscience. Our key areas of focus are depression, schizophrenia, Parkinson's disease and Alzheimer's disease.

An estimated 700 million people worldwide are living with psychiatric and neurological disorders 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 psychiatric and neurological disorders – we call this Progress in Mind.

Our approximately 5,300 employees in 55 countries are engaged in the entire value chain throughout research, development, manufacturing, marketing and sales. Our pipeline consists of several late-stage

development programmes and our products are available in more than 100 countries. We have research centres in China and Denmark and production facilities in China, Denmark, France and Italy. Lundbeck generated core revenue of DKK 14.6 billion in 2015 (EUR 2 billion; USD 2.2 billion).

For additional information, we encourage you to visit our corporate site www.lundbeck.com and connect with us on Twitter at @Lundbeck.

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] Kennedy, JL et al. (2014), The social and economic burden of treatment-resistant schizophrenia: a systematic literature review, International Clinical Psychopharmacology, 29(2), pp 63-76

[ii] Lieberman JA. Pathophysiologic mechanisms in the pathogenesis and clinical course of schizophrenia. J Clin Psychiatry. 1999; 60 (Suppl 12): 9-12.