



Corporate Release

Headline conclusions from the first out of three phase III studies on idalopirdine in Alzheimer's disease

- *In the first study, idalopirdine did not meet the primary endpoint*
- *Idalopirdine was safe and well tolerated*
- *The remaining two phase III studies are expected to report data in the first quarter 2017*

Valby, Denmark, 22 September 2016 - H. Lundbeck A/S (Lundbeck) today announced the headline conclusions from the first clinical phase III study, *STARSHINEⁱ*, in the ongoing phase III programme evaluating the efficacy of the investigational drug idalopirdine for the symptomatic treatment of patients with mild to moderate Alzheimer's disease.

In the *STARSHINE* study, idalopirdine showed a weak efficacy profile as neither of the two dosages used in the study met the primary endpoint of a reduction in the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-cog) total score when added to donepezil. In addition, the secondary endpoints also did not show separation from placebo. The overall safety profile for idalopirdine showed that idalopirdine was safe and well tolerated. Further analysis of the data is ongoing.

"We are disappointed about the outcome of this study," said Dr. Anders Gersel Pedersen, EVP and Chief Scientific Officer at Lundbeck. *"The phase II data were very encouraging but unfortunately, these data failed to replicate those findings".*

The two remaining studies, *STARBEAM* and *STARBRIGHTⁱⁱ*, in the phase III programme that currently are ongoing will continue as planned and data are expected in the first quarter of 2017.

About idalopirdine

Idalopirdine is a selective 5-HT₆ receptor antagonist. The 5-HT₆ receptor is expressed in brain regions involved in cognition, such as the cortex and the hippocampus, and modulates activity of multiple neurotransmitter systems.

Through 5-HT₆ receptors expressed on glutamatergic neurons and GABAergic interneurons, idalopirdine is believed to modulate the balance between excitation (glutamate) and inhibition (GABA) in the brain. When administered together with donepezil, idalopirdine potentiates the effects of the AChEI on ACh levels and on neuronal activity in the cortex and hippocampus.

Positive results of a 24-week clinical phase II trial with idalopirdine as adjunctive therapy in moderate Alzheimer's disease have been presented and to confirm the phase II findings, a large idalopirdine



phase III program as adjunct to acetylcholinesterase inhibitors in mild-moderate AD patients is ongoing. The development program is part of the alliance with Otsuka Pharmaceuticals Co. Ltd.

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About H. Lundbeck A/S

H. Lundbeck A/S (LUN.CO, LUN DC, HLUY) 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 5,000 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.

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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.

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ⁱ NCT01955161

ⁱⁱ NCT02006641 and NCT02006654