

Valby, 4 January 2019

## **Lundbeck initiates phase II-study of potential new treatment of schizophrenia**

**Lu AF11167 represents a new approach to treat negative symptoms of schizophrenia, which is currently a huge unmet medical need.**

H. Lundbeck A/S (Lundbeck) initiates a phase II-study (proof of concept-study) with the compound Lu AF11167 to confirm its potential as treatment of patients with schizophrenia who are experiencing persistent negative symptoms. Effective treatment of negative symptoms represents a huge unmet medical need for people with schizophrenia with no treatments specifically approved for this indication today.

Negative symptoms of schizophrenia refer to a deficit of normal function, usually manifested as lack of enjoyment, reduced social drive, poor motivation, reduced affective reactions, restricted speech and psychomotor retardation. Patients are often limited in their interaction with their surroundings, resulting in poor function that often prevents them from managing everyday situations and diminishes their quality of life<sup>i,ii,iii</sup>.

Lu AF11167 represents a new approach to treat negative symptoms of schizophrenia, working by inhibiting the activity of the PDE10-enzyme in the brain. This affects the signaling of the neurotransmitter dopamine in a manner that may specifically improve negative symptoms while positive symptoms remain controlled. Lu AF11167 is invented by Lundbeck.

“We are pleased to advance the clinical development of Lu AF11167, which has the potential to improve the treatment of patients with schizophrenia who are experiencing persistent negative symptoms. We look forward to learn more about this potential in the proof of concept-study”, says Mads Dalsgaard, Senior Vice President, Clinical Development at Lundbeck.

### **About the study**

The primary objective of the phase II study is to evaluate the efficacy on negative symptoms of two doses of Lu AF11167 versus placebo as monotherapy in patients with schizophrenia and persistent prominent negative symptoms. The secondary objective will be to evaluate the efficacy of Lu AF11167 on patients' functioning as well as the safety and tolerability of the compound. This 3-arm study will randomize a total of 240 patients (80 patients per arm) from various European countries.

### **About schizophrenia**

Schizophrenia is caused by an imbalance in the neurotransmitters facilitating the communication between neurons in the brain, leading to the perception

(seeing/hearing/thinking) of things that are not real. The factors that create this imbalance are not fully understood. Schizophrenia is a common form of severe mental illness that carries a notable 'stigma' and is often misunderstood. People with schizophrenia experience disturbed thoughts, emotions and behaviour, and they find it difficult to judge reality<sup>iv</sup>. This can have a major impact on the life of the individual and his/her family.

The World Health Organization estimates that over 21 million people suffer from schizophrenia, making it one of the top 20 causes of disability worldwide<sup>v</sup>. Schizophrenia affects people regardless of race, culture or social class. It typically starts in early adulthood (from age 20)<sup>vi</sup>, but it can develop at any age. Schizophrenia affects both men and women, although men tend to develop the condition slightly earlier in life<sup>vii</sup>. The risk of an individual developing schizophrenia during his or her lifetime is approximately 1 percent<sup>vi</sup>.

### Contacts

Mikkel Ballegaard Pedersen  
Journalist, Corp. Communication  
[mbap@lundbeck.com](mailto:mbap@lundbeck.com)  
+45 30 83 20 44

Mads Kronborg  
Senior Director, Corp. Communication  
[mavk@lundbeck.com](mailto:mavk@lundbeck.com)  
+45 36 43 40 00

### About Lundbeck

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.

Read more at [www.lundbeck.com/global/about-us/progress-in-mind](http://www.lundbeck.com/global/about-us/progress-in-mind).

Our approximately 5,000 employees in more than 50 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 than 100 countries. Our research centre is based in Denmark and our production facilities are located in Denmark, France and Italy. Lundbeck generated revenue of DKK 17.2 billion in 2017 (EUR 2.3 billion; USD 2.6 billion).

For additional information, we encourage you to visit our corporate site [www.lundbeck.com](http://www.lundbeck.com) and connect with us on Twitter at @Lundbeck.

- 
- <sup>i</sup> Correll CU. The Prevalence of Negative Symptoms in Schizophrenia and Their Impact on Patient Functioning and Course of Illness. *The Journal of Clinical Psychiatry*. 2013;74(02):e04.
- <sup>ii</sup> Patel R, Jayatilleke N, Broadbent M, et al. Negative symptoms in schizophrenia: a study in a large clinical sample of patients using a novel automated method. *BMJ Open*. 2015;5(9):e007619.
- <sup>iii</sup> Rabinowitz J, Berardo CG, Bugarski-Kirola D, Marder S. Association of prominent positive and prominent negative symptoms and functional health, well-being, healthcare-related quality of life and family burden: a CATIE analysis. *Schizophr Res*. 2013;150(2-3):339-342.
- <sup>iv</sup> American Psychiatric Association. Diagnostic and statistical manual of mental disorders, 5th edition (DSM-5). Washington, D.C.: American Psychiatric Association; 2013.
- <sup>v</sup> World Health Organization. Schizophrenia fact sheet, 2016. Available at <http://www.who.int/mediacentre/factsheets/fs397/en/>. Accessed May 2018.
- <sup>vi</sup> Tsuang MT, Faraone SV. Schizophrenia. Second edition. Oxford University Press Inc., New York: 2005.
- <sup>vii</sup> Ochoa S, Usall J, Cobo J, Labad X, Kulkarni J. Gender differences in schizophrenia and first-episode psychosis: a comprehensive literature review. *Schizophr Res Treatment*. 2012;2012:916198.