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# Corporate Release

# Lundbeck to acquire Prexton Therapeutics adding foliglurax in clinical phase II to its pipeline of innovative treatments for patients suffering from Parkinson's disease

- Lundbeck will make an upfront payment of EUR 100 million and the deal terms also include up to EUR 805 million in development, regulatory and sales milestones
- Foliglurax is a first-in-class treatment which entered clinical phase II testing in Parkinson's disease in July 2017
- There remains a large unmet need for effective treatments for Parkinson's patients to sustain the utility of dopaminergic therapies

Valby, Denmark, Oss, The Netherlands, 16 March 2018 - H. Lundbeck A/S (Lundbeck) and Prexton Therapeutics BV (Prexton) today announced signing of a definitive agreement in which Lundbeck will acquire Prexton. Under terms of the agreement, Lundbeck will pay EUR 100 million (approximately DKK 750 million) upfront and is furthermore required to later pay up to EUR 805 million (approximately DKK 6 billion) in development and sales milestones to the group of current owners.

By acquiring Prexton, Lundbeck will obtain global rights of an attractive compound (foliglurax) which currently is in clinical phase II testing for symptomatic treatment of *OFF*-time reduction in Parkinson's disease and dyskinesia including Levodopa Induced Dyskinesia (LID). First data from the ongoing clinical phase II programme is expected to be available during the first half of 2019.

"By acquiring Prexton, Lundbeck will obtain global rights to foliglurax, an exciting first-in-class compound, and gain full control of the asset," said Anders Götzsche, interim CEO and CFO at Lundbeck. "Foliglurax addresses high unmet needs with its potential indication in Parkinson's fitting perfectly within Lundbeck's core areas and this treatment option also appears to be highly interesting for patients, physicians and payors."

Foliglurax works by stimulating a specific glutamatergic target (mGluR4) which activates a compensatory neuronal system in the brain which is largely unaffected in Parkinson's disease. Animal models have convincingly demonstrated positive effects in models of Parkinson's disease. The aim is to treat the motor symptoms of Parkinson's disease, such as resting tremor, muscle rigidity and uncontrolled movements (dyskinesia).

#### **Deal terms**

Lundbeck will pay EUR 100 million upfront to the current investors of Prexton Therapeutics BV. Furthermore, Lundbeck is required to pay up to EUR 805 million in development, regulatory and sales



milestones depending on successful outcome of certain undisclosed milestones. More than half of the EUR 805 million is connected to sales milestones.

# Financial guidance

The content of this release will have no influence on Lundbeck's financial guidance for 2018, which was provided on 7 February 2018. The upfront payment will be capitalized in the balance sheet as an intangible asset and tested for impairment annually or whenever there is indication of impairment.

## **About Prexton**

Prexton is a biopharmaceutical company founded in 2012 by Francois Conquet and M Ventures, the corporate venture arm of Merck KGaA, their entrepreneurial partnership program, which supports the creation of spin-offs from Merck. Prexton applies a new scientific approach that fully integrates molecular, behavioral and chemistry technologies to address Parkinson's disease and other brain disorders. Prexton is based in Oss (The Netherlands) and in Geneva (Switzerland). Other major investors include Forbion, Seroba Life Sciences, Sunstone Capital and Ysios Capital.

# About foliglurax

Foliglurax (PTX002331) is a small-molecule positive allosteric modulator of group III metabotropic glutamate receptor 4 (mGluR4 PAM), for the potential oral treatment of Parkinson's disease.

A single- and multiple-ascending oral dose phase I trial (NCT02639221) in healthy volunteers with foliglurax was successfully completed in 2016. The results showed that foliglurax appears well-tolerated with a satisfactory pharmacokinetic (how the drug is processed in the body) profile.

In July 2017, Prexton initiated a phase II clinical trial (NCT03162874) with foliglurax. The trial will enroll around 165 Parkinson's patients in sites across six European countries (U.K., Germany, France, Austria, Spain, and Italy). The double-blinded, randomized, placebo-controlled, parallel-arm study will assess the effectiveness, safety, and tolerability of foliglurax in reducing motor complications of levodopa therapy in patients experiencing end-of-dose wearing-off and levodopa-induced dyskinesia.

Two groups will receive oral doses (10 mg and 30 mg) of the treatment over 28 days, in addition to their standard medication, incl. levodopa. A third group will receive placebo. The primary outcome measure will be the change in the daily awake "*OFF*"-time (i.e. time where the treatment does not work) based on patient diary entries between the start and end of treatment. The study is expected to be completed in 2019.

# About Parkinson's disease

Parkinson's is a devastating progressive neurological condition affecting around 6 million people worldwide. The disease is caused by the degeneration of dopaminergic brain cells. The main motor symptoms are resting tremor, muscle rigidity, and slowed movement (bradykinesia). Uncontrolled movements ('dyskinesia') is a debilitating complication to levodopa use.

Current treatments aim to replace dopamine or to mimic its effects. Patients are administered with the dopamine precursor levodopa. This treatment provides adequate symptomatic relief initially, but over



time, it loses efficacy as the disease progresses and patients experience serious debilitating, complications, such as increased *OFF* time and dyskinesia.

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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 Alzheimer's disease, depression, Parkinson's disease and schizophrenia.

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 production facilities 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 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.