



June 8, 2018

## Positive clinical phase III results of vortioxetine in Japanese adults with Major Depressive Disorder

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- | *New clinical phase III data from a study conducted in Japan demonstrate the efficacy of vortioxetine compared to placebo for the treatment of Major Depressive Disorder (MDD) in Japanese adults*
- | *Positive results suggest that vortioxetine may be a potential treatment option for Japanese patients with MDD in the future*
- | *Based on the current data package, Lundbeck and Takeda intend to initiate the process for registration in Japan*

**Valby, Denmark, and Osaka, Japan, 8 June 2018** - H. Lundbeck A/S (Lundbeck) and Takeda Pharmaceutical Company Limited (Takeda) today announced positive results from the pivotal study with vortioxetine in adults with Major Depressive Disorder conducted in Japan. Both companies intend to move forward with regulatory filing of vortioxetine later this year to the Ministry of Health, Labor and Welfare in Japan.

In April 2015, Takeda initiated the clinical phase III placebo-controlled study (NCT02389816) in MDD. Approximately 490 patients with recurrent MDD were randomized to receive vortioxetine (10 and 20 mg) or placebo. The primary endpoint was the change from baseline (i.e. the start of double-blind treatment) in the Montgomery—Åsberg Depression Rating Scale (MADRS) total score after 8 weeks of treatment.

### About Major Depressive Disorder (MDD)

MDD is a complex mental health illness that affects approximately 300 million people globally[1]. Also known as clinical depression, MDD is the leading cause of disability worldwide and a major contributor to the overall global burden of disease. MDD may trigger emotional, cognitive and physical symptoms, which includes depressed mood, loss of interest or pleasure, significant weight loss or gain or change in appetite, insomnia or hypersomnia, psychomotor agitation or retardation, fatigue or loss of energy, feelings of worthlessness or excessive guilt, diminished ability to think or concentrate, or indecisiveness, and recurrent suicidal ideation.

### About vortioxetine

The mechanism of the antidepressant effect of vortioxetine is not fully understood. It is an inhibitor of serotonin (5-HT) reuptake and that is thought to be a mechanism of its action. It is also an agonist at 5-HT<sub>1A</sub> receptors, a partial agonist at 5-HT<sub>1B</sub> receptors and an antagonist at 5-HT<sub>3</sub>, 5-HT<sub>1D</sub> and 5-HT<sub>7</sub> receptors. The contribution of each of these activities to vortioxetine's antidepressant effect has not been established. It is considered to be the first and only compound with this combination of pharmacodynamic activity. The clinical relevance of this is unknown.

Vortioxetine was discovered by Lundbeck researchers in Copenhagen, Denmark. The clinical trial program in Japan was conducted by Takeda.

The World Health Organization has issued an Anatomical Therapeutic Chemical (ATC) code for vortioxetine that places it in the category of "Other" antidepressants

The U.S. Food and Drug Administration (FDA) approved vortioxetine (Trintellix<sup>®</sup>) on 30 September 2013 for the treatment of MDD in adults. Vortioxetine is furthermore approved in 77 markets (including Europe, Canada, Chile, China, Mexico, Argentina, South Korea, Turkey, Australia, Hong Kong, Singapore and South Africa). It is available in more than 60 countries to date. Outside North America, vortioxetine is recognized as Brintellix<sup>®</sup>.

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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 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](http://www.lundbeck.com) and connect with us on Twitter at @Lundbeck.

## About Takeda Pharmaceutical Company Limited

Takeda Pharmaceutical Company Limited (TSE: 4502) is a global, research and development-driven pharmaceutical company committed to bringing better health and a brighter future to patients by translating science into life-changing medicines. Takeda focuses its R&D efforts on oncology, gastroenterology and neuroscience therapeutic areas plus vaccines. Takeda conducts R&D both internally and with partners to stay at the leading edge of innovation. Innovative products, especially in oncology and gastroenterology, as well as Takeda's presence in emerging markets, are currently fueling the growth of Takeda. Approximately 30,000 Takeda employees are committed to improving quality of life for patients, working with Takeda's partners in health care in more than 70 countries. For more information, visit <https://www.takeda.com/newsroom/>.

## 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.

[1] World Health Organization (WHO). Depression. <http://www.who.int/news-room/fact-sheets/detail/depression>. Accessed on 4 June 2018.

#### Attachment

- | [Brintellix-JAPAN UK Final](#)