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Corporate Release

FDA Psychopharmacologic Drug Advisory Committee supports the effectiveness of Brintellix® (vortioxetine) in treating certain aspects of cognitive dysfunction in Major Depressive Disorder (MDD)

- *The panel voted 8-2 that substantial evidence has been presented to support a claim of effectiveness for Brintellix for treating certain aspects of cognitive dysfunction in MDD*
- *The panel discussed that cognitive dysfunction in MDD represents an appropriate drug development target*

Valby, Denmark and Osaka, Japan, 4 February 2016 - H. Lundbeck A/S (Lundbeck) and Takeda Pharmaceutical Company Limited (Takeda) today announced that the U.S. Food and Drug Administration's (FDA) Psychopharmacologic Drugs Advisory Committee (PDAC) voted 8 to 2 that the companies presented substantial evidence to support the effectiveness of Brintellix (vortioxetine) for treating certain aspects of cognitive dysfunction in adults with Major Depressive Disorder (MDD). Earlier today, the committee also discussed that cognitive dysfunction in MDD represents an appropriate drug development target.

"*We are pleased with the Advisory Committee's recommendation that we have provided substantial evidence to support a claim of effectiveness of Brintellix for treating certain aspects of cognitive dysfunction in MDD*," said Anders Gersel Pedersen, Executive Vice President, Head of Drug Development at Lundbeck. "*This positive vote underscores the value of the robust research we've conducted on cognitive symptoms, which we've pursued knowing that patients need options. We are pleased that this sNDA represents the first regulatory submission to the FDA on this topic and we look forward to working with the Agency as they complete their review*."

"*Today's positive recommendation underscores the role of addressing the medical need of patients who experience cognitive dysfunction in depression*," said Emiliangelo Ratti, Senior Vice President, Head of CNS Therapeutic Area Unit, Takeda. "*Common cognitive symptoms include difficulty concentrating, indecisiveness and trouble thinking. Many of these symptoms are prevalent during major depressive episodes and can have an impact on depressed patients*."

The Advisory Committee provides the FDA with independent expert advice and recommendations. The committee's input will be considered by the Agency in its review of the Brintellix sNDA, which was accepted for review in August 2015. The FDA is expected to make a decision by 28 March 2016. The FDA is not bound by the committee's guidance.

Depression can be a combination of multiple symptoms, including cognitive dysfunction. The prevalence of cognitive dysfunction associated with depression is high. According to a three-year prospective study of people treated for depression, cognitive symptoms (defined as diminished ability to think or concentrate and/or indecisiveness) were reported 94 percent of the time during acute major depressive episodes and 44 percent of the time during remission.

The Advisory Committee reviewed data from the FOCUS and CONNECT studies, which were specifically designed to assess the effect of Brintellix on certain aspects of cognitive dysfunction in adult patients (18-65 years) with MDD. These two 8-week, randomized, double-blind, placebo-controlled studies of Brintellix 10 and 20 mg/day used a neuropsychological test of cognitive performance (the Digit Symbol Substitution Test or DSST).

The FDA approved Brintellix on 30 September 2013 for the treatment of MDD in adults. Brintellix is furthermore approved in 64 countries (including Europe, Brazil, Canada, Chile, Mexico, Argentina, South Korea, Turkey, Australia, Hong Kong, Singapore and South Africa).

For additional information on the 3 February 2016 Advisory Committee meeting please visit http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/ucm475314.htm.

About Brintellix (vortioxetine)

The mechanism of the antidepressant effect of Brintellix 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-HT1A receptors, a partial agonist at 5-HT_{1B} receptors and an antagonist at 5-HT_3, 5-HT_{1D} and 5-HT_7 receptors. The contribution of each of these activities to Brintellix'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.

Brintellix was discovered by Lundbeck researchers in Copenhagen, Denmark. The clinical trial program in the U.S. was conducted jointly by Lundbeck and Takeda, and Takeda holds the new drug application for the U.S. market. Brintellix is a trademark of H. Lundbeck A/S and is used under license by Takeda Pharmaceuticals U.S.A., Inc.

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

The most commonly observed adverse events in MDD patients treated with Brintellix in 6-8 week placebo-controlled studies (incidence greater than or equal to 5 percent and at least twice the rate of placebo) were nausea, constipation and vomiting. Overall, 5 to 8 percent of the patients who received Brintellix 5 to 20 mg/day in short-term trials discontinued treatment due to an adverse reaction, the most common being nausea, compared with 4 percent of placebo-treated patients in these studies. Brintellix and other antidepressants may cause serious side effects.

In clinical studies, Brintellix had no significant effect on body weight as measured by the mean change from baseline in 6-8 week placebo-controlled studies. In the 6-month, double-blind, placebo-controlled phase of a long-term study in patients who had responded to Brintellix during the initial 12-week, open-label phase, there was no significant effect on body weight between Brintellix and placebo-treated patients. Brintellix has not been associated with any clinically significant effects on vital signs, including systolic and diastolic blood pressure and heart rate, as measured in placebo-controlled studies.

The recommended starting dose of Brintellix is 10 mg once daily without regard to meals. The dose should then be increased to 20 mg/day, as tolerated, because higher doses demonstrated better treatment effects in trials conducted in the U.S. A dose decrease down to 5 mg/day may be considered for patients who do not tolerate higher doses. The available doses provide important flexibility for physicians to help address the variability of patient needs.

Brintellix is available as 5 mg, 10 mg and 20 mg tablets.

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About H. Lundbeck A/S

Lundbeck (LUN.CO, LUN DC, HLUYY) is a global pharmaceutical company specialized in brain diseases. 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 psychosis.

An estimated 700 million people worldwide are living with brain disease 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 brain disease — we call this *Progress in Mind*.

Our approximately 5,500 employees in 57 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. We have research centres in China and Denmark and production facilities in China, Denmark, France and Italy. Lundbeck generated core revenue of DKK 13.5 billion in 2014 (EUR 1.8 billion; USD 2.4 billion).

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

About Takeda Pharmaceutical Company Limited

Located in Osaka, Japan, Takeda (TSE: 4502) is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to strive towards better health for people worldwide through leading innovation in medicine.

Additional information about Takeda is available through its corporate website, www.takeda.com.

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.