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Corporate Release

FDA accepts a Supplemental New Drug Application for review of Brintellix® (vortioxetine) clinical trial data that assessed cognitive function in patients with major depressive disorder

Valby, Denmark and Osaka, Japan, 11 August 2015 - H. Lundbeck A/S (Lundbeck) and Takeda Pharmaceutical Company Limited (Takeda) announced today the US Food and Drug Administration (FDA) has accepted a supplemental New Drug Application (sNDA) for review to add clinical data regarding the effect of Brintellix (vortioxetine) on certain aspects of cognitive dysfunction in adults with Major Depressive Disorder (MDD) to the current product label. Brintellix is currently approved and available in the US for the treatment of MDD in adults. The FDA is expected to take action on this filing by 28 March 2016.

Depression includes a range of symptoms including cognitive ones[i]. The cognitive symptoms of depression may go unrecognized by both healthcare providers and patients.[i,ii] Common cognitive complaints include difficulty concentrating, indecisiveness, trouble thinking and forgetfulness.[i] These symptoms are common and many of them often persist between major depressive episodes.[i,ii] 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% of the time during major depressive episodes and 44% of the time between major depressive episodes (or during periods of partial remission).[ii]

"*Cognitive symptoms are often present in patients suffering from MDD and reducing these symptoms can be challenging*," explains John Zajecka, M.D., Associate Professor of Psychiatry, Rush University Medical Center, in Chicago. "*Many patients continue to experience certain cognitive and other symptoms even after improvement in their MDD*."

The sNDA is primarily based on the *FOCUS* and *CONNECT* studies, which were specifically designed to assess the effect of Brintellix on certain aspects of cognitive function in adult patients with MDD utilizing objective measures of cognitive function.[iii,iv] These two 8-week, randomized, double-blind, placebo-controlled studies of Brintellix 10 and 20 mg/day used a well-established neuropsychological test (the Digit Symbol Substitution Test or DSST).[iii,iv] The DSST performance measurement involves executive function, processing speed and attention.[iii,iv]

The FDA approved Brintellix on 30 September 2013 for the treatment of MDD in adults. Brintellix is furthermore approved in 55 countries (including Europe, Canada, Chile, Mexico, Argentina, South Korea, Turkey, Australia, Hong Kong, Singapore and South Africa). It is available in approximately 30 countries to date.

About Brintellix (vortioxetine)

Brintellix is an inhibitor of serotonin (5-HT) reuptake and is also an agonist at 5-HT_{1A} receptors, a partial agonist at 5-HT_{1B} receptors and an antagonist at 5-HT_3, 5-HT_{1D} and 5-HT_7 receptors. Brintellix is considered to be the first and only compound with this combination of pharmacodynamic activity, although the mechanism of the antidepressant effect of Brintellix is not fully understood and has not been established.

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.

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

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About Lundbeck

H. Lundbeck A/S (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 alcohol dependence, Alzheimer's disease, bipolar disorder, depression/anxiety, epilepsy, Huntington's disease, Parkinson's disease, schizophrenia and symptomatic neurogenic orthostatic hypotension (NOH).

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.

Read more at www.lundbeck.com/global/about-us/progress-in-mind.

Our approximately 6,000 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 programs and our products are available in more than 100 countries. We have research centers in China, Denmark and the United States and production facilities in China, Denmark, France and Italy. Lundbeck generated revenue of approximately DKK 13.5 billion in 2014 (EUR 1.8 billion; USD 2.4 billion).

Lundbeck's shares are listed on the stock exchange in Copenhagen under the symbol "LUN". Lundbeck has a sponsored Level 1 ADR program listed in the US (OTC) under the symbol "HLUYY".

For additional information, we encourage you to visit our corporate site www.lundbeck.com.

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.

About Takeda Pharmaceuticals U.S.A., Inc. and Takeda Development Center Americas, Inc.

Based in Deerfield, Ill., Takeda Pharmaceuticals U.S.A., Inc. and Takeda Development Center Americas, Inc. are subsidiaries of Takeda Pharmaceutical Company Limited, the largest pharmaceutical company in Japan. The respective companies currently market oral diabetes, CNS, rheumatology, gastroenterology and cardiovascular disease treatments and seek to bring innovative products to people through a pipeline that includes compounds in development for diabetes, gastroenterology, neurology and other conditions. To learn more about these Takeda companies, visit www.takeda.us.

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.

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[i] Diagnostic and Statistical Manual of Mental Disorders (DSM-5). (5th ed., 155-188). America Psychiatric Association, 2013.

[ii] Conradi, H., Ormel, J., & De Jonge, P. (2011). Presence of individual (residual) symptoms during depressive episodes and periods of remission: A 3-year prospective study. Psychological Medicine, 41(06), 1165-1174.

[iii] McIntyre R.S., Olsen K. (2014). A randomized, double-blind, placebo-controlled study of vortioxetine on cognitive function in depressed adults. Int J Neuropsychopharm.17, 1557-1567.

[iv] Mahableshwarkar A.R., Zajecka J., Jacobson W., et al. (2015). A Randomized, Placebo-Controlled, Active-Reference, Double-Blind, Flexible-Doze Study of the Efficacy of Vortioxetine on Cognitive Function in Major Depressive Disorder. Neuropsychopharm. 40, 2025-2037.