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Corporate Release

Lundbeck receives European marketing authorization for Brintellix for the treatment of adults with Major Depressive Episodes

- *Approval is based on an extensive clinical program including positive efficacy data in 9 short-term studies, including one in the elderly, and one positive relapse-prevention study*
- *Brintellix has a novel multimodal pharmacological profile that may translate into therapeutic benefits in depression that current therapies do not sufficiently address*
- *Major depression is a leading cause of disability and lost work productivity affecting more than 30 million people in Europe*[i]

Valby, Denmark, 27 December 2013 - H. Lundbeck A/S (Lundbeck) today announced that the European Commission granted marketing authorization for Brintellix (vortioxetine) for the treatment of adults with Major Depressive Episodes, commonly referred to as depression. The European approval follows approval by the U.S. Food and Drug Administration (FDA) in September 2013.

"*The approval of Brintellix marks yet another step for Lundbeck in a very successful year*," said Executive Vice President Anders Gersel Pedersen, Head of Research & Development at Lundbeck. "*With its novel multimodal mechanism of action, we are confident that Brintellix advances both the science and the treatment of a complex and heterogeneous disease consisting of emotional, physical and cognitive symptoms that make it difficult for many patients to achieve full recovery from their disease*".

The approval of Brintellix was based on the review of one of the most comprehensive global clinical development programs in depression, involving more than 7,000 patients. Approximately 4,000 patients were treated with Brintellix in 12 short-term (6 to 8 weeks), placebo-controlled studies of patients with an acute episode of major depression. In 9 of the 12 studies, Brintellix showed statistically significant and clinically relevant effects on depression relative to placebo. One of these studies was a dedicated study in the elderly. The symptoms of depression were assessed using the Montgomery and Åsberg Depression Scale (MADRS) or Hamilton Depression Rating Scale (HAM-D_{24}). The clinical relevance was supported by significant effects observed in the proportions of responders and remitters and in the improvement in the Clinical Global Impression – Global Improvement (CGI-I) score. A dose response was observed with the efficacy of Brintellix increasing with higher doses.

Furthermore, efficacy of Brintellix has also been demonstrated in patients with an acute episode of major depression and with a suboptimal response to treatment with an SSRI or SNRI. In a 12-week head-to-head study (REVIVE) versus the most recently approved antidepressant in the EU, agomelatine. Brintellix was significantly superior to agomelatine after both 8 (primary end point) and 12

weeks, as measured by improvement in the MADRS total score and by the proportion of remitters and improvement in the CGI-I and Sheehan Disability Scale (SDS) scores[ii].

The recommended starting and treatment dose of Brintellix is 10 mg once daily in adults less than 65 years of age. The dose may be increased to a maximum of 20 mg once daily or decreased to a minimum of 5 mg once daily, depending on individual patient response.

The multimodal pharmacological profile of Brintellix is considered responsible for the antidepressant and anxiolytic-like effects of the compound and the potential improvement of cognitive performance, learning and memory observed with the product in pre-clinical studies.

The approval will be applicable to all 28 European Union member states plus Iceland, Liechtenstein and Norway. Subject to the completion of pricing and reimbursement discussions, Lundbeck expects to launch Brintellix in its first markets in the second half of 2014.

About the studies included in the regulatory dossier

Brintellix has been studied in a comprehensive global clinical development program that included more than 7,000 patients. Close to 4,000 patients were treated with Brintellix in 12 short-term (6 to 8 weeks), placebo-controlled studies of major depressive disorder. In 9 of the 12 studies, Brintellix showed statistically significant and clinically relevant effects on depression relative to placebo; one of these studies was a dedicated study in the elderly. The symptoms of depression were assessed using the Montgomery and Åsberg Depression Scale (MADRS) or Hamilton Depression Rating Scale (HAM-D_{24}). In addition, significant effect was observed in the proportions of responders and remitters and in the improvement in the Clinical Global Impression — Global Improvement (CGI-I) score. The efficacy of Brintellix increased with higher doses.

The long-term effect of Brintellix was demonstrated in a 24-64 week, relapse-prevention study. Brintellix treatment resulted in a statistically significant longer time to relapse of depression compared to placebo. Treatment with Brintellix reduced the risk of relapse by 50% compared to placebo.

The most common adverse reaction in patients treated with Brintellix was nausea, which was usually mild to moderate and occurred within the first two weeks of treatment. The reactions were usually transient and did not generally lead to discontinuation of therapy.

In short- and long-term clinical studies, Brintellix had no significant effect on body weight. The incidence of self-reported adverse sexual reactions was low and similar to placebo in the short- and long-term studies. In studies using the ASEX scale, no clinically relevant difference to placebo in symptoms of sexual dysfunction was seen in doses up to 10 mg/day of Brintellix. For doses above 10 mg/day an increase in TESD was seen compared to placebo. Brintellix has not been associated with any clinically significant effects on vital signs, including systolic and diastolic blood pressure and heart rate.

About Brintellix (vortioxetine)

The mechanism of action of vortioxetine is thought to be related to its direct modulation of serotonergic receptor activity and inhibition of the serotonin (5-HT) transporter. Nonclinical data indicate that vortioxetine is a 5-HT_3, 5-HT_7, and 5-HT_{1D} receptor antagonist, 5-HT_{1B} receptor partial agonist, 5-HT_{1A}

receptor agonist and inhibitor of the 5-HT transporter, leading to modulation of neurotransmission in several systems. In vivo non-clinical studies have demonstrated that Brintellix modulates neuronal firing and neurotransmitter release in multiple systems, resulting in enhanced levels of serotonin, noradrenaline, dopamine, acetylcholine and histamine, reduction of GABA and increase of glutamate in specific areas of the brain. This multimodal activity is considered responsible for the antidepressant and anxiolytic-like effects and the improvement of cognitive function, learning and memory observed with vortioxetine in animal studies. However, the precise contribution of the individual targets to the observed pharmacodynamic profile remains unclear and caution should be applied when extrapolating animal data directly to man.

The World Health Organization has issued a new Anatomical Therapeutic Chemical (ATC) code for Brintellix for implementation in 2014.

Brintellix was discovered by Lundbeck researchers in Copenhagen, Denmark.

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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 50 years, we have been at the forefront of research within neuroscience. Our development and distribution of pioneering treatments continues to make a difference to people living with brain diseases. Our key areas of focus are alcohol dependence, Alzheimer's disease, depression/anxiety, epilepsy, Huntington's disease, Parkinson's disease, schizophrenia and stroke.

Our 5,800 employees in 57 countries are engaged in the entire value chain throughout research, development, production, marketing and sales, and are committed to improving the quality of life of people living with brain diseases. Our pipeline consists of several late-stage development programs and our products are available in more 100 countries. We have research centers in China, Denmark and the United States, and production facilities in China, Denmark, France, Italy and Mexico. Lundbeck generated revenue of approximately DKK 15 billion in 2012 (EUR 2 billion; USD 2.6 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.

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] J.Olesen, et al. Eur J Neurology. 2012; 19:155-162

[ii] L. Häggström, R.Z. Nielsen and M. Dragheim: A randomised, double-blind, active controlled study of vortioxetine (10-20 mg/day) versus agomelatine (25-50 mg/day) in adults with major depressive disorder with inadequate response to antidepressant treatment. EPA 2013