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Corporate Release

Vortioxetine, a new multimodal agent in development for the treatment of major depression, shows effects on cognitive function in several preclinical animal models

- *New preclinical data for vortioxetine presented at the American Psychiatric Association demonstrate differences from other antidepressants (SSRI/SNRI) in studies of cognitive function*
- *In animals the data show the effect of vortioxetine in models assessing a variety of cognitive functions, including attention, memory and executive function*
- *These preclinical data provide additional evidence for the mode of action of vortioxetine and the critical role of activity at specific serotonin receptors to explain the differences observed from SSRI and SNRI antidepressants*

Valby, Denmark, 22 May 2013 - H. Lundbeck A/S (Lundbeck) today announced positive results from four pre-clinical animal studies with (vortioxetine, an investigational agent under review with the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and other health agencies for the treatment of major depression. In these studies the objective was to further study the pharmacological profile of vortioxetine and the potential effects in models of depressive disorders assessing a variety of cognitive functions, including attention, memory and executive function. These studies were presented at the 2013 American Psychiatric Association Annual Meeting (APA) in San Francisco:

- Poster NR11-36: Modulation of GABAergic activity via 5-HT_3 receptor antagonism is involved in vortioxetine's (Lu AA21004) in vivo pharmacodynamic profile
- Poster NR11-58: Vortioxetine (Lu AA21004), an investigational multimodal antidepressant, reverses executive function deficits in rats treated subchronically with PCP
- Poster NR11-59: Vortioxetine (Lu AA21004), an investigational multimodal antidepressant: Differentiation from currently used antidepressants in rodent models
- Poster NR11-60: Vortioxetine improves a reversal learning deficit in rats induced by serotonin depletion with PCPA

Vortioxetine was demonstrated to modulate GABA-ergic activity in a cellular model, an effect of vortioxetine's multimodal activity. Vortioxetine also demonstrated improvement in attention, memory and executive function in animal models. The preclinical data presented at the conference also show a different profile of vortioxetine compared to fluoxetine and escitalopram (SSRIs) as well as duloxetine (an SNRI), which were not active in these animal models. While animal studies may not be directly applicable to human use, the new preclinical data provide supportive evidence that vortioxetine has the potential to improve cognitive symptoms frequently occurring in depressive disorder, such as impaired

attention, memory and executive function. The preclinical data further suggest that the potential cognitive effects of vortioxetine in animals may be related to its activity at specific serotonin receptors.

Unlike SSRIs or SNRIs, vortioxetine has a multimodal mode action that is thought to work through a combination of two complementary mechanisms of action: receptor activity modulation and reuptake inhibition. The multimodal action may translate into distinct clinical effects in the treatment of major depressive disorder (MDD), which is being investigated further in clinical studies.

"*These preclinical results on cognitive function further highlight the pharmacological profile of vortioxetine. Current widely used SSRIs and SNRIs are in many patients only partially effective with high rates of residual symptoms and relapse. Cognitive symptoms are key symptoms of depression and are challenging to address with currently available treatments",* says Anders Gersel Pedersen, Head of Research and Development at Lundbeck. *"We believe that there is a growing pharmacologic as well as pre-clinical rationale for the effect of vortioxetine on cognitive function in depression."*

In May 2012 Lundbeck presented results from a clinical study in elderly patients with MDD, where direct effects on neuropsychological tests as DSST (Digit Symbol Substitution Test) and RAVLT (Ray Auditory Verbal Learning Test) were demonstrated. These tests evaluate cognitive functions such as executive function, attention memory and processing speed. Currently, Lundbeck and its development partner Takeda are conducting two clinical studies in adult patients with major depression using these scales as key outcome measures.

About vortioxetine (Lu AA21004)

Vortioxetine (currently under review with the FDA) is an investigational antidepressant with multimodal activity that is thought to work through a combination of two mechanisms of action: receptor activity modulations and reuptake inhibition. In vitro studies 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 serotonin (5-HT) transporter (SERT). In vivo non-clinical studies have demonstrated that vortioxetine enhances levels of the neurotransmitters serotonin, noradrenaline, dopamine, acetylcholine and histamine in specific areas of the brain.

In 2012, Lundbeck filed vortioxetine (formerly described as Lu AA21004) for regulatory approval for the indication of MDD in the EU, Canada and other markets, as well as in the US with its co-development partner, Takeda.

About major depression

Major depression is a highly prevalent, serious and debilitating medical disorder. The disease can be described as a complex syndrome of emotional, cognitive and physical symptoms.

The significant clinical heterogeneity of the disorder is frequently cited as a reason for the limited efficacy of currently available antidepressants. In a landmark naturalistic clinical trial, more than 50% of patients remained symptomatic following first-line treatment, and nearly one-third failed to achieve full resolution of depressive symptoms after four established treatments [i].

The tolerability of antidepressants and patients' concerns about side effects negatively affect patient outcomes. Patients with MDD who experience at least one severe side effect are twice as likely to discontinue treatment prematurely. Common reasons for premature treatment discontinuation include weight gain, and gastrointestinal and sexual side effects.

MDD is the leading worldwide cause of years lost due to disability, and projected to be the biggest contributor to the worldwide burden of disease by 2030. It is estimated that between a quarter and a third of the population will develop at least one episode of major depression during their life-time and of these as many as two thirds will have recurrent episodes, and one third will develop a chronic condition.

Depression is associated with significant functional impairment and reduced quality of life. Many patients experience a range of symptoms of the disease that include cognitive symptoms such as difficulty concentrating, forgetfulness and inability to make decisions. Persistence of cognitive symptoms in patients with MDD can contribute to impaired work function and predict poor occupational outcome. Additional treatment strategies are needed to prevent and treat these common and debilitating symptoms of depression.

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About Lundbeck

Lundbeck is a global pharmaceutical company highly committed to improving the quality of life of people living with brain diseases. For this purpose, Lundbeck is engaged in the entire value chain throughout research, development, production, marketing and sales of pharmaceuticals across the world. The company's products are targeted at disorders such as depression and anxiety, psychotic disorders, epilepsy, Huntington's, Alzheimer's and Parkinson's diseases. Lundbeck's pipeline consists of several mid- to late- stage development programs.

Lundbeck employs more than 5,800 people worldwide, 2,000 of whom are based in Denmark. We have employees in 57 countries, and our products are registered in more than 100 countries. We have research centers in Denmark, China and the United States and production facilities in Italy, France, Mexico, China and Denmark. Lundbeck generated revenue of approximately DKK 15 billion in 2012. Lundbeck's shares are listed on the stock exchange in Copenhagen under the symbol "LUN". Lundbeck has a sponsored Level 1 ADR programme 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.

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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] Rush et al; Am J Psych 2006; 163: 1905-1917