H. Lundbeck A/S

Ottiliavej 9
DK-2500 Valby, Copenhagen
CVR number: 56759913

Tel +45 36 30 13 11
Fax +45 36 43 82 62

E-mail investor@lundbeck.com
www.lundbeck.com

Corporate Release No 485

12 December 2012

FDA accepts Takeda and Lundbeck's filing for review of Brintellix (vortioxetine) for the treatment of major depression

- *FDA has determined that the New Drug Application filed in October 2012 is sufficiently complete to permit a substantive review*
- *Upon the acceptance of the filing by the FDA, Lundbeck is to receive a milestone of USD 50 million (approximately DKK 285 million) from Takeda*

H. Lundbeck A/S (Lundbeck) announced today that the U.S. Food and Drug Administration (FDA) has accepted the submission of a New Drug Application (NDA) for Brintellix™ (vortioxetine) for the treatment of major depressive disorder (MDD) in adult patients. Brintellix (pronounced "brin′-tel-ix") is the proposed global trade name for vortioxetine.

According to the timelines established by the Prescription Drug User Fee Act (PDUFA), the review of the NDA is targeted for completion by 2 October, 2013.

The NDA includes positive data from six short-term studies and one long-term maintenance study. The vortioxetine global clinical development program included more than 7,500 individuals aged 18 to 88 years old exposed to the drug. Major depression, often referred to as depression, is a common, debilitating illness affecting around 15 million Americans and 121 million people worldwide. Depression was the third leading contributor to the global burden of disease in 2004 and is projected to be the leading contributor to the worldwide burden of disease by 2030.

About Brintellix

Brintellix (vortioxetine) is under investigation as an 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.

Across the doses of 5-20mg, the most commonly observed adverse reactions in MDD patients treated with vortioxetine in placebo-controlled studies (incidence ≥5% and at least twice the rate of placebo) were: nausea, constipation and vomiting. Overall, 6.5% of the patients who received vortioxetine discontinued treatment due to an adverse reaction, compared with 3.8% of placebo-treated patients in these studies. Nausea was the most common adverse reaction reported as a reason for discontinuation and considered to be drug-related.

About Takeda and Lundbeck alliance

In September 2007, Lundbeck and Takeda formed a strategic alliance for the exclusive co-development and co-commercialization in the United States and Japan of several compounds in Lundbeck's pipeline for mood and anxiety disorders. The partnership initially focuses on co-development and co-commercialization of the two most advanced compounds in Lundbeck's pipeline for mood and anxiety disorders, Brintellix and tedatioxetine (Lu AA24530). If approved, the companies plan to co-promote the products in the United States and Japan.

Financial guidance

The content of this release will have no influence on the Lundbeck Group's financial guidance for 2012, which was provided on 8 February 2012 in connection with the release of the financial results for 2011, and further specified in connection with the announcement of the restructuring plan on 14 June 2012.

Lundbeck contacts

Investors:

Palle Holm Olesen
Chief Specialist, Head of Investor Relations
palo@lundbeck.com
+45 36 43 24 26

Magnus Thorstholm Jensen
Investor Relations Officer
matj@lundbeck.com
+45 36 43 38 16

Media:

Simon Mehl Augustesen
International Media Specialist
smeh@lundbeck.com
+45 36 43 49 80

About Lundbeck

H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) is an international pharmaceutical company highly committed to improving the quality of life for people suffering from brain disorders. For this purpose, Lundbeck is engaged in the research, development, production, marketing and sale of pharmaceuticals across the world. The company’s products are targeted at disorders such as depression and anxiety, psychotic disorders, epilepsy and Huntington’s, Alzheimer’s and Parkinson’s diseases.

Lundbeck was founded in 1915 by Hans Lundbeck in Copenhagen, Denmark. Today Lundbeck employs approximately 6,000 people worldwide. Lundbeck is one of the world’s leading pharmaceutical companies working with brain disorders. In 2011, the company's revenue was DKK 16.0 billion (approximately EUR 2.1 billion or USD 3.0 billion). For more information, please visit 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.