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NDA for aripiprazole depot formulation for maintenance treatment of adult patients with schizophrenia accepted by the FDA

- *Submission based on data from pivotal trials evaluating efficacy, safety and tolerability in patients suffering from schizophrenia*
- *Lundbeck has co-development and co-commercialisation rights to aripiprazole depot formulation in North and Latin America as well as Europe, Australia and some other countries*

H. Lundbeck A/S (Lundbeck) and Otsuka Pharmaceutical Co., Ltd. (Otsuka) announced today that the US Food and Drug Administration (FDA) has determined that a new drug application (NDA) for Otsuka's investigational once-monthly aripiprazole depot formulation for the indication of maintenance treatment of schizophrenia in adults is sufficiently complete to permit a substantive review.

Otsuka and Lundbeck entered into a long-term CNS agreement for up to five innovative psychiatric and neuroscience products on 11 November 2011. The two companies are collaborating on the co-development and co-commercialization (following approval of regulatory authorities) of aripiprazole depot formulation worldwide.

The NDA is based on data from a phase III clinical study designed to evaluate the efficacy, safety and tolerability of the intramuscular formulation as a maintenance treatment in patients with schizophrenia. In October 2010, an independent data monitoring committee recommended the early termination of the Phase III, 52-week, placebo-controlled, intramuscular depot aripiprazole trial. This was due to the study successfully meeting efficacy criteria at a protocol-specified interim analysis.

"Aripiprazole, a dopamine, D₂ partial agonist with its unique pharmacological profile, has been prescribed around the world while recognized as an important long-term treatment option for patients with schizophrenia," says Dr. Taro Iwamoto, President and Representative Director, Otsuka Pharmaceutical Co., Ltd. *"The submission of this NDA for the once monthly aripiprazole depot formulation is the first step in providing another treatment option for the current problems faced by patients with schizophrenia."*

"We are very pleased that our new partner, Otsuka, has submitted an NDA for the aripiprazole depot formulation as this will potentially provide patients suffering from schizophrenia in the US with a new treatment option," says Ulf Wiinberg, President & Chief Executive Officer at Lundbeck, and continues:



"Schizophrenia is a serious disease and there is still a great need to offer patients improved maintenance therapies and for therapies that can improve compliance."

About Schizophrenia

Schizophrenia is a disease characterized by a distortion in the process of thinking and of emotional responsiveness. It most commonly manifests as auditory hallucinations, paranoid or bizarre delusions, or disorganized speech and thinking, and is accompanied by significant social or occupational dysfunction. Onset of symptoms typically occurs in young adulthood and is a chronic condition that often requires life-long treatment to mitigate symptoms. It has been estimated that schizophrenia affects approximately 1% of the adult population in the US and Europe. In the US, there are approximately 2.2 million adults with schizophrenia, prevalent equally in both genders¹.

About aripiprazole depot formulation

Aripiprazole depot formulation is a sterile lyophilized cake that when reconstituted with sterile water for injection forms an injectable suspension. This formulation was studied as a once-monthly injection for the maintenance treatment of schizophrenia. In October 2010, Otsuka announced that the Phase III US registration study, a multicenter, randomized, double-blind, placebo-controlled study, was terminated early by an Independent Data Monitoring Committee following meeting efficacy criteria at a protocol-specified interim analysis.

Financial guidance

The content of this release will have no influence on the Lundbeck Group's financial guidance for 2011 which was provided on 24 February 2011 in connection with the release of the financial results for 2010.

¹ Source: National Institute of Mental Health



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About Otsuka

Founded in 1964, Otsuka Pharmaceutical Co., Ltd. is a global healthcare company with the corporate philosophy, "Otsuka-people creating new products for better health worldwide." Otsuka researches, develops, manufactures and markets innovative and original products, with a focus on pharmaceutical products for the treatment of diseases, and consumer products for the maintenance of everyday health. Otsuka is committed to being a corporation that creates global value, adhering to high ethical standards required of a company involved in human health and life, maintaining a dynamic corporate culture, and working in harmony with local communities and the natural environment. For more information, please visit www.otsuka.co.jp/en.

About Otsuka Pharmaceutical Development & Commercialization, Inc.

Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC) is involved in conducting all phases of clinical research and development of innovative healthcare products to address unmet medical needs. OPDC is well established in the scientific community as a globally-focused organization that plays a leadership role in the research and development of Otsuka's ethical healthcare products.

The company is dedicated to improving the quality of human life and patient health around the world with a strong commitment to research and development in the areas of neuroscience, cardiovascular diseases, and oncology. OPDC is part of the Otsuka Group companies. For more information, visit www.otsuka-us.com. OPDC is a subsidiary of Otsuka America, Inc., which is wholly owned by Otsuka Pharmaceutical Co., Ltd.

About Lundbeck

H. Lundbeck A/S (LUN.CO, LUN DC, HLUKY) 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, schizophrenia, insomnia, 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 5,900 people worldwide. Lundbeck is one of the world's leading pharmaceutical companies working with brain disorders. In 2010, the company's revenue was DKK 14.8 billion (approximately EUR 2.0 billion or USD 2.6 billion). For more information, please visit www.lundbeck.com.