



## H. Lundbeck A/S

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Corporate Release No 481

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### US Food and Drug Administration accepts the resubmission of New Drug Application for aripiprazole depot formulation

- *FDA establishes PDUFA action date of 28 February 2013.*
- *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) today announced that the US Food and Drug Administration (FDA) has accepted for review the resubmission of the New Drug Application (NDA) for aripiprazole depot formulation, a potential treatment for schizophrenia. FDA stated that this resubmission constituted a complete class 2 response to their action letter of July 26, 2012. The Prescription Drug User Fee Act (PDUFA) goal date is 28 February 2013.

The NDA was resubmitted in response to a Complete Response Letter (CRL) Otsuka received from the FDA on 26 July 2012 which cited deficiencies from a recent inspection of a third party supplier.

### 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.



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## About Otsuka Pharmaceutical Co., Ltd.

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 the 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.

Otsuka Pharmaceutical Co., Ltd. is a wholly owned subsidiary of Otsuka Holdings Co., Ltd., the holding company for the Otsuka Group. The Otsuka Group has business operations in 24 countries and regions around the world, with consolidated sales of ¥1,154.6 billion for fiscal year 2011. For more information, visit [www.otsuka.co.jp/en](http://www.otsuka.co.jp/en).

## 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](http://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.