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### **Lundbeck and Otsuka Pharmaceutical sign historic agreement to deliver innovative medicines targeting psychiatric disorders worldwide**

- *Lundbeck and Otsuka, two companies with a rich CNS heritage, form a global alliance to focus on delivering up to five innovative psychiatric and neuroscience products in a multi-billion DKK deal*
- *Lundbeck and Otsuka will work closely together to develop and commercialise new medicines to patients in an area of substantial unmet medical needs*
- *Lundbeck is granted co-development and co-commercialisation rights to aripiprazole depot formulation in North and Latin America as well as Europe, Australia and some other countries*
- *Lundbeck is granted co-development and co-commercialisation rights to OPC-34712, which recently entered clinical phase III studies in schizophrenia and major depressive disorder*
- *With this collaboration Lundbeck significantly expands its portfolio of innovative psychiatry products and can establish Lundbeck within the US psychiatry community*
- *The deal significantly enhances Lundbeck's long-term growth prospects. Increased commercialisation and R&D costs is likely to put pressure on earnings in the period 2012-14, however Lundbeck's long-term floor guidance is maintained*

H. Lundbeck A/S (Lundbeck) and Otsuka Pharmaceutical Co., Ltd. (Otsuka) today announced a development and commercialisation agreement for up to five products in the psychiatry field, including aripiprazole depot formulation and OPC-34712 from Otsuka and up to three highly innovative earlier stage projects from Lundbeck.

The long-term alliance including the near-term projects from Otsuka and the earlier stage psychiatric disorder portfolio from Lundbeck enhances both companies' portfolios of new medical offerings covering all aspects of severity in the treatment of patients suffering from psychotic, mood and behavioural disorders. In addition, this collaboration agreement will accelerate the development of Lundbeck's most advanced schizophrenia projects.

*"We are very pleased to have entered into this collaboration with Otsuka. With the addition of aripiprazole depot formulation and OPC-34712, Lundbeck has significantly broadened its growing psychiatry portfolio with exciting and unique treatments in an area of high unmet needs,"* said Ulf



Wiinberg, President & Chief Executive Officer at Lundbeck. *"This collaboration further strengthens our US platform and allows us to be introduced with the US psychiatry community already in 2013."*

*"We are very excited that Otsuka and Lundbeck have entered into a co-development and co-commercialisation agreement for aripiprazole depot formulation and OPC-34712, both potential key drivers of future growth for Otsuka's CNS business," said Dr. Taro Iwamoto, President and Representative Director, Otsuka. "Lundbeck's expertise in developing depression and anxiety treatments and Otsuka's expertise in developing anti-psychotics will maximise the medical and commercial value of Otsuka's portfolio in CNS. In addition, our partnership with Lundbeck will enable us to establish a strong platform to deliver these compounds to patients who need them in Europe, South America, Oceania, the BRIC countries and other countries around the world. Our collaboration will lead to the next generation of innovation by developing Lundbeck's three new compounds."*

The alliance is a sales and cost share agreement. Under the terms of the agreement, Lundbeck will make an upfront payment upon signing of USD 200 million (approximately DKK 1.1 billion).

Otsuka will receive up to approximately USD 1.4 billion (approximately DKK 7.6 billion) in total from Lundbeck in upfront payment and development and regulatory milestone payments. Including sales milestones, Lundbeck will pay up to approximately USD 1.8 billion (approximately DKK 9.7 billion) to Otsuka. Both companies will share the sales as well as development and commercialisation costs based on the agreement.

Lundbeck is granted co-development and co-commercialisation rights to aripiprazole depot formulation and OPC-34712 in North and Latin America, Europe, Australia and some other countries. With the comparable efficacy and safety profile to already marketed aripiprazole formulations, aripiprazole depot formulation has been developed to reduce the chance of reoccurrence of symptoms for the patients who sometimes forget to take their medication as well as to enhance the convenience of medication with a once monthly dosing. The New Drug Application (NDA) for aripiprazole depot formulation is expected soon to be submitted to the US Food and Drug Administration (FDA), and Lundbeck expects that the Marketing Authorisation Application (MAA) is to be submitted in Europe during 2013.

OPC-34712 is a novel investigational psychotherapeutic compound developed to provide improved efficacy and tolerability (e.g., less akathisia, restlessness and/or insomnia). The compound has broad activity across multiple monoamine systems and exhibits reduced partial agonist activity at D<sub>2</sub> dopamine receptors and enhanced affinity for specific serotonin receptors. OPC-34712 has entered into clinical phase III trial for schizophrenia and adjunctive treatment of major depressive disorder (MDD).

Under the terms of the agreement, Otsuka has an option to enter into co-development and co-commercialisation of up to three early stage compounds in Lundbeck's R&D pipeline in certain geographical regions. The three compounds to be included in this collaboration are under discussion between Lundbeck and Otsuka.

Otsuka brings a strong presence in the North American and Asian central nervous system (CNS) markets, and Lundbeck compliments their position with a strong presence in Europe, Canada and Latin America. Combined, both companies reach most of the global CNS market.



## Lundbeck's and Otsuka's shared vision

Otsuka started its business from Naruto City, Shikoku Island, Japan in 1921 and Lundbeck began its business in Copenhagen, Denmark in 1915. Both companies will collaborate for the benefit of patients with mental disorders and together pursue a world-class partnership in the field of CNS disorders.

At a time when many pharmaceutical companies have experienced challenges in bringing new CNS therapies to market, Otsuka and Lundbeck will take a different—and true to their entrepreneurial cultures—unconventional approach to delivering new treatment options. Both companies are committed to creating truly valuable drugs that benefit patients and their families.

Otsuka began its research and development efforts in the CNS area in the 1970s. Abilify<sup>®</sup> (aripiprazole), Otsuka's top-selling CNS drug, was the result of a quarter of a century of commitment, followed by a successful collaboration with Bristol-Myers Squibb Company, which remains, and to which Otsuka remains fully committed. Abilify<sup>®</sup> is currently marketed in more than 65 countries and regions. The net sales of Abilify<sup>®</sup> in the fiscal year 2010 were approximately USD 4.5 billion (approximately DKK 24 billion) and is now one of the top three products among anti-psychotic agents worldwide<sup>1</sup>. Otsuka has a portfolio of psychiatric and neuroscience products in development for its next contribution to patients worldwide.

Lundbeck markets a number of different pharmaceuticals for the treatment of CNS disorders. The most recently launched compounds include: Cipralex<sup>®</sup>/Lexapro<sup>®</sup> (depression), the best selling product of the company with the global sales of approximately USD 4 billion (approximately DKK 22 billion); Ebixa<sup>®</sup> (Alzheimer's disease); Azilect<sup>®</sup> (Parkinson's disease); Xenazine<sup>®</sup> (chorea associated with Huntington's disease); Serdolect<sup>®</sup> (schizophrenia); and Sabril<sup>®</sup> (epilepsy).

Both companies share similarities in their corporate cultures including the focus on truly innovative approaches, taking unconventional paths to drug discovery and commercialisation, and sharing the belief that doing so eventually leads to innovation.

## Financial considerations of the deal

The alliance is a sales and cost share agreement. Under the terms of the agreement, Lundbeck will make an upfront payment upon signing of USD 200 million (approximately DKK 1.1 billion).

Otsuka will in total receive approximately USD 1.4 billion (approximately DKK 7.6 billion) from Lundbeck as upfront payment and development and regulatory milestone payments. Including sales milestones Lundbeck will pay up to approximately USD 1.8 billion (approximately DKK 9.7 billion) to Otsuka. Both companies will share the sales as well as development and commercialisation costs based on the agreement.

For aripiprazole depot formulation, Lundbeck will obtain 50% of net sales in Europe (EU5 and the Nordic countries) and Canada and 20% of net sales in the US from Otsuka. The cost incurred for the development and promotion will be shared in the same ratio. Otsuka holds the rights in many of the

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<sup>1</sup> According to the survey conducted by Cegedim Strategic Data K.K



Asian countries including Japan, as well as Turkey and Egypt. For the remaining markets in the Lundbeck territories, Lundbeck will market the compound and Otsuka will supply the bulk at a price agreed upon as a percentage of sales.

For OPC-34712, Lundbeck will obtain 50% of net sales in Europe (EU5 and the Nordic countries) and Canada and 45% of net sales in the US from Otsuka. The cost incurred for the promotion will be shared in the same ratio. Otsuka holds the rights in many of the Asian countries including Japan, Turkey and Egypt. For the remaining markets in the Lundbeck territories, Lundbeck will market the compound, and Otsuka will supply the bulk at a price agreed upon as a percentage of sales. For the development costs of OPC-34712, Otsuka will be responsible up to a certain amount and equally share the costs with Lundbeck afterwards.

In co-commercialisation countries, the parties will share sales efforts and costs in accordance with the territory split. In the US, Canada, EU5 and the Nordic countries, Otsuka will book all sales. In the rest of Europe and the world, excluding many of the Asian countries, Turkey and Egypt, Lundbeck will book all sales and take full responsibility for commercialisation. Otsuka will retain the rights to participate in the co-development and co-marketing when it establishes a sales organisation in Lundbeck's territory.

In November 2010, Lundbeck provided its long-term floor guidance. According to this guidance, Lundbeck expects to generate a minimum annual revenue and EBIT of DKK 14 billion and DKK 2 billion, respectively, in the period 2012-14. Following the co-commercialisation agreement with Otsuka, Lundbeck faces increased costs in connection with commercialisation of aripiprazole depot formulation as well as development cost for OPC-34712. Lundbeck remains committed to exceed the long-term floor guidance.

Lundbeck expects to continue its strong cash flow generation, and in the period 2012-2014 plans to pay out a dividend in the upper end of the payout target of 25-35%.

### 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.

### 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 has been evaluated as a once-monthly injection for the maintenance treatment of schizophrenia.

Otsuka's *Aripiprazole Intramuscular Depot Study in Schizophrenia-US* is a phase III clinical study of the depot formulation of aripiprazole that was designed to evaluate the efficacy, safety and tolerability of the intramuscular formulation as a maintenance treatment in patients with schizophrenia. The US registration study (31-07-246) was a multicentre, randomised, double-blind, placebo-controlled study, originally scheduled for a 52 week duration, which incorporated an interim analysis after achievement of 50% of the 125 events needed to complete the study. This interim analysis was conducted in June 2010, and the independent data monitoring committee determined that the interim analysis met the established termination criteria and recommended that the study be stopped.



## About OPC-34712

OPC-34712 is a novel investigational psychotherapeutic compound developed to provide improved efficacy and tolerability (e.g., less akathisia, restlessness and/or insomnia). The compound has broad activity across multiple monoamine systems and exhibits reduced partial agonist activity at D<sub>2</sub> dopamine receptors and enhanced affinity for specific serotonin receptors. OPC-34712 has entered into clinical phase III trial for schizophrenia and adjunctive treatment of MDD.

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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 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 23 countries and regions around the world, with consolidated sales of JPY 1,090.2 billion for fiscal year 2010.

### 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](http://www.lundbeck.com).