



## Current Agreements

### Dealdoc

#### **Co-development and co-promotion agreement for up to five innovative psychiatric and neuroscience products**

Otsuka  
Lundbeck

Nov 10 2011

# Co-development and co-promotion agreement for up to five innovative psychiatric and neuroscience products

<b>Companies:</b>	<a href="#">Otsuka</a> <a href="#">Lundbeck</a>
<b>Announcement date:</b>	Nov 10 2011
<b>Deal value, US\$m:</b>	1800.0 : sum of upfront and milestone payments

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## Details

<b>Announcement date:</b>	Nov 10 2011
<b>Industry sectors:</b>	Bigpharma Pharmaceutical
<b>Therapy areas:</b>	Psychiatry » Depression » Moderate Psychiatry » Depression » Severe Psychiatry » Schizophrenia
<b>Technology types:</b>	Drug delivery » Oral delivery » Delayed release Small molecules Bigpharma outlicensing Co-development
<b>Deal components:</b>	Co-market Co-promotion Licensing
<b>Stages of development:</b>	Phase I Phase II Phase III
<b>Geographic focus:</b>	Worldwide

## Financials

<b>Deal value, US\$m:</b>	1800.0 : sum of upfront and milestone payments
<b>Upfront, US\$m:</b>	200.0 : upfront payment
<b>Milestones, US\$m:</b>	1200.0 : development and regulatory milestone payments 400.0 : sales milestone payments 50.0 : of net sales in Europe (EU5 and the 4 Nordic countries) and Canada for aripiprazole depot formulation
<b>Royalty rates, %:</b>	20.0 : of net sales in US for aripiprazole depot formulation 50.0 : of net sales in Europe (EU5 and the 4 Nordic countries) and Canada for OPC-34712 45.0 : of net sales in US for OPC-34712
<b>Funding, US\$m:</b>	n/d : both companies will share the sales and development and commercialization costs based on the agreement

## Termsheet

Long-term agreement for the development and commercialization of up to five innovative psychiatric and neuroscience products worldwide.

The agreement covers up to five early and late stage compounds in development.

The two late stage compounds are from Otsuka: aripiprazole depot formulation and OPC-34712.

Otsuka receives the rights to enter into co-development, and eventual co-promotion following approval, of up to three compounds after Phase IIb clinical trials.

The alliance is a sales and cost share agreement.

Lundbeck will make an upfront payment upon signing of USD 200 million.

Otsuka will in total receive up to approximately USD 1.4 billion from Lundbeck as upfront payment and development and regulatory milestone payments.

With the addition of sales milestones in connection, Lundbeck will pay up to approximately USD 1.8 billion to Otsuka.

Both companies will share the sales and development and commercialization costs based on the agreement.

For aripiprazole depot formulation, Lundbeck will receive 50% of net sales in Europe (EU5 and the 4 Nordic countries) and Canada and 20% of net sales in the U.S. 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 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 product at a price of agreed percentage of the sales.

For OPC-34712, Lundbeck will receive 50% of net sales in Europe (EU5 and the 4 Nordic countries) and Canada and 45% of net sales in the U.S. 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, 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 product at a price of agreed percentage of the sales.

For the development costs of OPC-34712, Otsuka will be responsible up to certain amount and equally share the costs afterwards.

In co-commercialization countries, the parties will share sales efforts and costs in accordance with the territory split.

In the U.S., Canada, EU5 and the 4 Nordic countries, Otsuka will book all sales.

In the rest of Europe and the world, excluding many of the Asian countries, as well as Turkey and Egypt, Lundbeck will book all sales and take full responsibility for commercialization.

Otsuka will retain the rights to participate in the co-development and co-marketing when it establishes a sales organization in Lundbeck's territory.

## **Press Release**

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S Sign Historic Agreement to Deliver Innovative Medicines with Focus on Psychiatric Disorders Worldwide

– Starting with a USD 1.8 billion agreement to co-develop and co-commercialize aripiprazole depot formulation and OPC-34712, two companies with a rich CNS heritage form one of the largest global alliances to focus on delivering up to five innovative psychiatric and neuroscience products–

TOKYO & COPENHAGEN, Denmark--(BUSINESS WIRE)--Otsuka Pharmaceutical Co., Ltd. (Otsuka) and H. Lundbeck A/S (Lundbeck) today announced that they have entered into a long-term agreement for the development and commercialization of up to five innovative psychiatric and neuroscience products worldwide. Otsuka and Lundbeck signed the historic agreement during a ceremony held at Tokushima City in Tokushima, Japan on November 11, 2011.

The agreement covers up to five early and late stage compounds in development. The two late stage compounds are from Otsuka: aripiprazole depot formulation and OPC-34712. Otsuka receives the rights to enter into co-development, and eventual co-promotion following approval, of up

to three compounds after Phase IIb clinical trials.

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. Otsuka will in total receive up to approximately USD 1.4 billion from Lundbeck as upfront payment and development and regulatory milestone payments. With the addition of sales milestones in connection, Lundbeck will pay up to approximately USD 1.8 billion to Otsuka. Both companies will share the sales and development and commercialization costs based on the agreement.

For aripiprazole depot formulation, Lundbeck will receive 50% of net sales in Europe (EU5 and the 4 Nordic countries) and Canada and 20% of net sales in the U.S. 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 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 product at a price of agreed percentage of the sales.

For OPC-34712, Lundbeck will receive 50% of net sales in Europe (EU5 and the 4 Nordic countries) and Canada and 45% of net sales in the U.S. 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, 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 product at a price of agreed percentage of the sales. For the development costs of OPC-34712, Otsuka will be responsible up to certain amount and equally share the costs afterwards.

In co-commercialization countries, the parties will share sales efforts and costs in accordance with the territory split. In the U.S., Canada, EU5 and the 4 Nordic countries, Otsuka will book all sales. In the rest of Europe and the world, excluding many of the Asian countries, as well as Turkey and Egypt, Lundbeck will book all sales and take full responsibility for commercialization. Otsuka will retain the rights to participate in the co-development and co-marketing when it establishes a sales organization in Lundbeck's territory.

Otsuka brings a strong presence in the North American and Asian CNS markets, and Lundbeck complements Otsuka's position with a strong presence in Europe. Combined, both companies reach most of the global CNS market.

**OTSUKA AND LUNDBECK'S SHARED VISION** Otsuka started its business from Tokushima, Shikoku Island in 1921, while Lundbeck began its business in Copenhagen, Sjælland Island in 1915. Both companies believe the collaboration will benefit patients with mental disorders and together will pursue a world class partnership in the field of central nervous system 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 valuable drugs that benefit mental health patients and their families.

Otsuka began its research and development efforts in the CNS area in the 1970s. ABILIFY® (INN: aripiprazole), Otsuka's top-selling CNS drug, was the result of a quarter century commitment, followed by a successful collaboration with Bristol-Myers Squibb Company, which collaboration remains ongoing, and to which Otsuka remains fully committed. ABILIFY is currently marketed in more than 65 countries and regions. ABILIFY net sales in fiscal year 2010 were approximately USD 4.5 billion (JPY 392.6 billion) <sup>1</sup> and ABILIFY is now one of the top-three<sup>2</sup> products among anti-psychotic agents worldwide. Otsuka has a portfolio of psychiatric and neuroscience products in development for its next contribution to patients worldwide. <sup>1</sup>: Calculated by the average rate (87.79 JPY/USD) through the fiscal year ended March 31 <sup>2</sup>: According to the survey conducted by Cegedim Strategic Data K.K

Lundbeck markets a number of different pharmaceuticals for the treatment of central nervous system disorders. Recently launched compounds include: Ciprallex® and Lexapro® (depression; INN escitalopram), the latter being the company's highest selling product with global sales of approximately USD \$4 billion, Ebixa® (Alzheimer's disease; INN: memantine), Azilect® (Parkinson's disease; INN: rasagiline), Xenazine® (chorea associated with Huntington's disease; INN: tetrabenazine), Serdolect® (schizophrenia; INN: sertindole) and Sabril® (epilepsy; INN: Vigabatrin).

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

**QUOTES FROM REPRESENTATIVES** "We are very excited that Otsuka and Lundbeck have entered into a co-development and co-commercialization 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 Pharmaceutical Co., Ltd. "Lundbeck's expertise in developing depression and anxiety treatments and Otsuka's expertise in developing anti-psychotics will maximize 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<sup>3</sup>, BRICs<sup>4</sup> and around the world. Our collaboration will lead to the next generation of innovation by co-developing Lundbeck's three new compounds." <sup>3</sup>: Australia, New Zealand and other countries <sup>4</sup>: Brazil, Russia, India, China

"We are very pleased to have entered into this collaboration with Otsuka," said Ulf Wiinberg, President & Chief Executive Officer, Lundbeck. "With the addition of aripiprazole depot formulation and OPC-34712, Lundbeck has significantly broadened its growing psychiatry portfolio with an exciting and unique potential treatment in an area of high unmet need. This collaboration allows us to be introduced to the U.S. psychiatry community as soon as 2013."

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-U.S. 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 U.S. registrational study (31-07-246) was a multicenter, randomized, double-blind, placebo-controlled study, originally scheduled for a 52 week duration, that 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 potentially provide improved efficacy and tolerability over established therapies for the treatment of schizophrenia and the adjunctive treatment of major depressive disorder (MDD). The compound has broad activity across multiple monoamine systems including partial agonist activity at D2 dopamine receptors and enhanced affinity for specific serotonin receptors. OPC-34712 is currently in clinical phase III testing for schizophrenia and adjunctive treatment of MDD.

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

About H. Lundbeck A/S 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 central nervous system (CNS) 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 CNS 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).

## **Filing Data**

*Not available.*

## **Contract**

*Not available.*