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**For Immediate Release**

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**Otsuka and Lundbeck Announce U.S. Food and Drug Administration Acknowledges Receipt of Resubmission of New Drug Application for Aripiprazole Depot Formulation**

Otsuka Pharmaceutical Co., Ltd., a subsidiary company of Otsuka Holdings Co., Ltd., announced that that the U.S. Food and Drug Administration (FDA) acknowledged receipt of the resubmission of the New Drug Application (NDA) for aripiprazole depot formulation, a potential treatment for schizophrenia.

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(Tokyo, Japan and Copenhagen, Denmark, September 12) – Otsuka Pharmaceutical Co., Ltd. (Otsuka) and H. Lundbeck A/S (Lundbeck) announced today that the U.S. Food and Drug Administration (FDA) has acknowledged receipt of 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 and that the Prescription Drug User Fee Act (PDUFA) goal date is February 28, 2013.

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

### **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 25 countries and regions around the world, with consolidated sales of JPY 1.15 trillion (approximately USD 14.0 billion or EUR 10.5 billion) for fiscal year 2011. For more information, visit [www.otsuka.co.jp/en](http://www.otsuka.co.jp/en).

### **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 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's U.S. business is based in Deerfield, Illinois. To learn more about Lundbeck in the U.S., visit [www.lundbeckus.com](http://www.lundbeckus.com).

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 2.2 billion or USD 3.0 billion). For more information, please visit [www.lundbeck.com](http://www.lundbeck.com).