



July 24, 2014

For Immediate Release

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OTSUKA AND LUNDBECK SUBMIT NEW DRUG APPLICATION IN THE US FOR BREXPIPRAZOLE FOR THE TREATMENT OF SCHIZOPHRENIA AND AS ADJUNCTIVE THERAPY FOR THE TREATMENT OF MAJOR DEPRESSIVE DISORDER

Otsuka Pharmaceutical Co., Ltd., a subsidiary company of Otsuka Holdings Co., Ltd., and H. Lundbeck A/S today announced the submission of a New Drug Application (NDA) to the United States Food and Drug Administration (FDA) for brexpiprazole for the treatment of schizophrenia and as adjunctive treatment of major depressive disorder (MDD).

Tokyo, Japan and Copenhagen, Denmark –July 14, 2014 – Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S, today announced the submission of a New Drug Application (NDA) to the United States Food and Drug Administration (FDA) for brexpiprazole for the treatment of schizophrenia and as adjunctive treatment of major depressive disorder (MDD).

The clinical development program for brexpiprazole included more than 6,500 participants of whom more than 5,300 received brexpiprazole. The NDA is supported by seven completed Phase 2 or 3 clinical studies in the proposed indications. Following the submission the U.S. Food & Drug Administration (FDA) will determine if the NDA is sufficiently complete to allow for a substantive review of the data; a decision from the FDA on initiation of the substantive review is expected in September 2014.

Brexpiprazole is a novel investigational compound discovered by Otsuka and under co-development with Lundbeck. Brexpiprazole is a serotonin-dopamine activity modulator (SDAM) that acts as a partial agonist at 5-HT_{1A} and dopamine D_2 receptors at similar potency, and an antagonist at 5-HT_{2A} and noradrenaline alpha_{1B/2C} receptors.

About Otsuka Pharmaceutical Co., Ltd.

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 nutraceutical products for the maintenance of everyday health.

In pharmaceuticals, Otsuka is a leading firm in the challenging area of mental health and also has research programs on several under-addressed diseases including tuberculosis, a significant global public health issue. These commitments illustrate more powerfully than words how Otsuka is a "big venture" company at heart, applying a youthful spirit of creativity in everything it does.

Otsuka Pharmaceutical Co., Ltd., which employees approximately 28,700 people worldwide, is a wholly owned subsidiary of Otsuka Holdings Co., Ltd., the holding company for the Otsuka Group that is headquartered in Tokyo, Japan. The chairman Akihiko Otsuka is the third generation of Otsuka family members to lead the business, whose origins date from 1921. The Otsuka Group has business operations in 25 countries and regions around the world, with consolidated sales of approximately USD 14.1 billion for fiscal year 2013 (4/1/2013-3/31/2014.) Otsuka Pharmaceutical welcomes you to visit its global website at https://www.otsuka.co.jp/en.

About H. Lundbeck A/S

Lundbeck is a global pharmaceutical company highly committed to improving the quality of life of people living with brain diseases. For this purpose, Lundbeck is engaged in the entire value chain throughout research, development, production, marketing and sales of pharmaceuticals across the world. The company's products are targeted at disorders such as depression and anxiety, psychotic disorders, epilepsy, Huntington's, Alzheimer's and Parkinson's diseases. Lundbeck's pipeline consists of several mid- to late-stage development programs.

We have employees in 57 countries, and our products are registered in more than 100 countries. We have research centers in Denmark, China and the United States and production facilities in Italy, France, Mexico, China and Denmark. Lundbeck generated revenue of approximately DKK 15 billion in 2012. For additional information, we encourage you to visit our corporate site www.lundbeck.com.

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