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For Immediate Release

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**OTSUKA AND LUNDBECK'S ONCE-MONTHLY
ABILIFY MAINTENA® (ARIPIPRAZOLE) NOW APPROVED IN EUROPE FOR
MAINTENANCE TREATMENT OF SCHIZOPHRENIA IN ADULT PATIENTS
STABILIZED WITH ORAL ARIPIPRAZOLE**

Otsuka Pharmaceutical Co., Ltd. (Otsuka), a subsidiary company of Otsuka Holdings Co., Ltd., and H. Lundbeck A/S (Lundbeck) announced marketing authorization approval from the European Commission for Abilify Maintena (aripiprazole) for maintenance treatment of schizophrenia in adult patients stabilized with oral aripiprazole.

The consolidated business forecast of fiscal 2013 announced by Otsuka Holdings on November 13, 2013 will not be changed.

- Preventing relapse is critical in the treatment of schizophrenia. Pivotal studies, that supported the EU submission, demonstrate that Abilify Maintena can reduce the risk of relapse relative to placebo and is non-inferior to oral aripiprazole in patients with schizophrenia^{1,2}
- The approval of Abilify Maintena now provides patients with schizophrenia access to a once-monthly formulation with established efficacy together with a tolerability profile that is comparable to that of oral ABILIFY® (aripiprazole)²
- At the end of the randomized, double-blind treatment phase in one of the pivotal trials, 93 percent of patients reported being extremely, very or somewhat satisfied with Abilify Maintena treatment³
- Abilify Maintena is the only dopamine D2 partial agonist in a once-monthly, injectable form to receive marketing authorization in Europe for maintenance treatment of schizophrenia
- Abilify Maintena will be the first commercialized product in Europe from the global alliance between Otsuka and Lundbeck which is focused on developing Central Nervous System (CNS) therapies worldwide

(Tokyo, Japan and Copenhagen, Denmark, Thursday, November 21, 2013) – Otsuka Pharmaceutical Co., Ltd. (Otsuka) and H. Lundbeck A/S (Lundbeck) today announced marketing authorization approval from the European Commission for Abilify Maintena (aripiprazole), an intramuscular (IM) once-monthly injectable formulation for maintenance treatment of schizophrenia in adult patients stabilized with oral aripiprazole.

Abilify Maintena reduces the risk of relapse relative to placebo over the long-term and provides effective treatment of schizophrenia.^{1,2} It has a tolerability profile similar to oral aripiprazole¹, and demonstrated statistically significant benefits on patients' personal and social functioning as compared to placebo.^{1,4} 93 percent of patients treated with Abilify Maintena were extremely, very or somewhat satisfied with their treatment at the end of the double-blind treatment phase.⁴

“We strongly believe the schizophrenia community will welcome the availability of Abilify Maintena to help improve outcomes for patients living with schizophrenia. As a company, our focus is to develop treatments to help protect against relapse and preserve brain function,” said Ole Vahlgren, CEO & President, Otsuka Europe. “We must partner with health care professionals and caregivers to help patients get the best treatments that focus on reducing the risk of relapse.”

“Studies have shown that the early use of long-acting injectables can prevent a person with schizophrenia from experiencing a relapse,”⁵ said Ole Chrintz, SVP International Markets & Europe, Lundbeck. “Efficacy is important, but a treatment for a chronic condition such as schizophrenia also needs to be well tolerated so patients will stay on it over the long-term. We believe Abilify Maintena meets this need.”^{1,2,3}

About the Studies

The efficacy of Abilify Maintena was demonstrated in two double-blind, Phase III, randomized trials. The safety profile for Abilify Maintena was demonstrated to be similar to that of oral ABILIFY. The most frequently observed adverse drug reactions (ADRs) reported in ≥ 5 percent of patients in two double-blind controlled clinical trials of Abilify Maintena were weight increases (9.0 percent), akathisia (7.9 percent), insomnia (5.8 percent), and injection site pain (5.1 percent).^{1,2}

About Abilify Maintena

Abilify Maintena is the only dopamine D2 partial agonist in once-monthly, injectable form to receive marketing authorization for maintenance treatment in schizophrenia. Physicians now have an alternative treatment option, with a tolerability profile comparable to the well-established oral ABILIFY, to address the on-going need to reduce the risk of relapse in patients with schizophrenia.

The European label states that Abilify Maintena is a powder and solvent for prolonged-release suspension for intra-muscular (IM) injection. It is a once-monthly formulation of aripiprazole in a sterile lyophilized powder that is reconstituted with sterile water. Abilify Maintena is indicated for maintenance treatment of schizophrenia in adult patients stabilized with oral aripiprazole.

After the first injection, treatment with 10 mg to 20 mg oral aripiprazole should be continued for 14 consecutive days to maintain therapeutic aripiprazole concentrations during initiation of therapy.

About Schizophrenia and Disease Relapse

Schizophrenia is a disease characterized by a distortion in the process of thinking and of emotional responsiveness. It most commonly manifests as hallucinations, paranoid or bizarre delusions, or disorganized speech and thinking, and is accompanied by significant social or occupational dysfunction. Onset of symptoms typically occurs in young adulthood, and the condition is chronic, often requiring lifelong treatment to mitigate symptoms.

Relapse of schizophrenia refers to an exacerbation or acute psychotic break that is characterised primarily by the emergence of positive symptoms such as hallucinations, delusions and disordered thinking.⁶

Relapse can occur when a patient no longer responds to antipsychotic medication, does not take the medication as prescribed, or stops taking their medication altogether. There are many reasons patients stop taking their medication, including poor insight about their illness, side effects from current treatments, complicated medication regimen or lack of support from family.⁷ Abilify Maintena is able to significantly reduce the risk of relapse in patients with schizophrenia.¹

It has been estimated that schizophrenia affects approximately one percent of the adult population in the U.S. and Europe, and approximately 24 million people worldwide.^{8,9} In Europe there are approximately 4.4 million adults with schizophrenia,¹⁰ prevalent equally in both genders.^{11,12} While there is no cure for the disease, symptoms and risk of relapse can be managed in most patients with appropriate antipsychotic treatment. However, when the disease is not managed, patients are at increased risk of disease relapse, which can cause the re-emergence or worsening of psychotic symptoms.¹³

Schizophrenia places a significant burden on society. It is regarded among the most financially costly illnesses and is according to the World Health Organization (WHO), the 8th leading cause of DALYs (lost healthy years) worldwide among patients between the age of 15-44.¹¹ With 50 percent of patients not receiving appropriate care and 80 percent of patients relapsing within the first 5 years,¹⁴ there is a significant unmet need to be addressed in schizophrenia.

About the Lundbeck and Otsuka Global Alliance

Lundbeck and Otsuka established a global alliance in November 2011 to bring to bear their considerable experience and resources in the CNS area to introduce next-generation treatments for conditions such as schizophrenia, depression, Alzheimer's disease and alcohol dependency.

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 for 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 is a wholly owned subsidiary of Otsuka Holdings Co., Ltd., the holding company for the Otsuka Group. The chairman Akihiko Otsuka is the third generation of Otsuka family members to lead the business, whose origins date from 1921. The Otsuka Group employs approximately 42,000 people globally and its products are available in more than 80 countries worldwide. Consolidated sales were approximately €10 billion or USD 13 billion for fiscal year 2012 (4/1/2012-3/31/2013). 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 programmes.

Lundbeck employs more than 5,800 people worldwide, 2,000 of whom are based in Denmark. We have research 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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