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Press release

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Lundbeck and Otsuka initiate European launch of Abilify Maintena[®] (aripiprazole), a once-monthly formulation for the treatment of schizophrenia

Denmark is the first country in Europe where Abilify Maintena[®] is fully reimbursed and accessible to people diagnosed with schizophrenia.

- *Abilify Maintena[®] gives patients long-term protection from relapse*, one of the key goals in the treatment of schizophrenia, by delaying time to and reducing the risk of relapse¹. Relapse, particularly in the early course of the disease, can have a profound detrimental impact on the patients' long-term prognosis².*
- *Abilify Maintena[®] provides people diagnosed with schizophrenia access to a once-monthly formulation with a favourable tolerability profile that is comparable to that of oral ABILIFY[®] (aripiprazole)³.*
- *In Europe, relapses, and the resulting progressive functional decline can lead to increased healthcare costs, mainly driven by recurrent and prolonged hospital stays.⁴*

H. Lundbeck A/S (Lundbeck) and Otsuka Pharmaceutical Europe Ltd. (Otsuka) today announced the launch of Abilify Maintena in Europe following approval by the European Commission in November 2013. Abilify Maintena is now available in a number of European countries and is progressing through the various Healthcare Authorities that provide access to patients. Denmark is the first European country where Abilify Maintena is fully reimbursed and accessible to people with schizophrenia, and more than ten markets are expected to launch by the end of 2014.

Abilify Maintena (aripiprazole) is an intramuscular (IM), once-monthly injectable formulation for maintenance treatment of schizophrenia in adult patients stabilized with oral aripiprazole.

In clinical trials, Abilify Maintena provided protection from relapse over the long term with over 90% of patients remaining relapse-free at the end of the study period^{5,6}. It offers long-term control of positive and negative symptoms and can help preserve patients' personal and social functioning while offering a favourable tolerability profile similar to oral aripiprazole⁶

“We are very pleased to bring once-monthly Abilify Maintena to people diagnosed with schizophrenia” said Ole Chrintz, Senior Vice President, International Markets and Europe at Lundbeck. “Patients early in the course of their disease may have the most to gain from a long-acting treatment that reduces their risk of relapse over the long term and can help them maintain personal and social functioning.”

Ole Vahlgren, CEO & President, Otsuka Europe noted *“The clinical and economic burden of schizophrenia is substantial. The majority of patients who try long-acting injections tend to prefer them over their previous oral formulations. We are committed to working with local governments and healthcare authorities to make Abilify Maintena available to patients in every European country”.*

Abilify Maintena was approved by the FDA for the treatment of schizophrenia in the US in February 2013 and has recently received a marketing authorization for the maintenance treatment of schizophrenia in stabilized adult patients in Canada.

**relapse = an exacerbation or acute psychotic break that is characterised primarily by the emergence of positive symptoms such as hallucinations, delusions and disordered thinking⁹*

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About the Studies³

The efficacy of Abilify Maintena[®] (aripiprazole) was demonstrated in two double-blind, phase III, randomized trials. The safety profile for Abilify Maintena was shown to be similar to that of oral ABILIFY[®] (aripiprazole). 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).

About Abilify Maintena® (aripiprazole)⁷

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

Abilify Maintena is indicated for maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole.

Abilify Maintena is administered as a prolonged-release suspension for intra-muscular (IM) injection. It is a once-monthly formulation of aripiprazole in a sterile lyophilised powder that is reconstituted with sterile water.

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 characterised by a distortion in the process of thinking and of emotional responsiveness. It most commonly manifests as hallucinations, paranoid or bizarre delusions, or disorganised 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.⁸

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.⁹

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.^{10,11} In Europe there are approximately 4.4 million adults with schizophrenia (including people with schizophrenia spectrum disorders),¹² prevalent equally in both genders.^{13,14} 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.¹⁵

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. With 50 percent of patients not receiving appropriate care and 80 percent of patients relapsing within the first 5 years,¹⁶ 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 Lundbeck

H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) is a global pharmaceutical company specialized in brain diseases. For more than 50 years, we have been at the forefront of research within neuroscience. Our development and distribution of pioneering treatments continues to make a difference to people living with brain diseases. Our key areas of focus are alcohol dependence, Alzheimer's disease, depression/anxiety, epilepsy, Huntington's disease, Parkinson's disease, schizophrenia and stroke.

Our approximately 6,000 employees in 57 countries are engaged in the entire value chain throughout research, development, production, marketing and sales, and are committed to improving the quality of life of people living with brain diseases. Our pipeline consists of several late-stage development programs and our products are available in more 100 countries. We have research centers in China, Denmark and the United States, and production facilities in China, Denmark, France, Italy and Mexico. Lundbeck generated revenue of approximately DKK 15 billion in 2013 (EUR 2.0 billion; USD 2.7 billion).

For further information please visit www.lundbeck.com.

About Otsuka

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/>

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