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Corporate Release

FDA accepts for review Otsuka Pharmaceutical and Lundbeck's supplemental New Drug Application to expand Abilify Maintena® (aripiprazole) labelling

Valby, Denmark and Princeton, New Jersey, USA, 30 April 2014 - H. Lundbeck A/S (Lundbeck) and Otsuka America Pharmaceutical, Inc. (OAPI) today announced the U.S. Food and Drug Administration (FDA) has accepted for review a supplemental New Drug Application (sNDA) for the proposed expanded labeling of Abilify Maintena (aripiprazole) for extended-release injectable suspension to support broader use of the drug for treatment of patients in the acute phase of schizophrenia. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target date of 7 December 2014 to complete its review.

The sNDA submission was based on a 12-week study of patients with schizophrenia hospitalized and experiencing an acute exacerbation of symptoms. The study demonstrated efficacy on the primary endpoint of Positive and Negative Syndrome Scale (PANSS) total score ($p<0.0001$). Data showed Abilify Maintena was also effective on the key secondary endpoint of Clinical Global Impressions – Severity (CGI-S score, $p<0.0001$). The three most common adverse events reported by patients receiving Abilify Maintena were weight gain, headache and akathisia. The full study results have been submitted for publication in a scientific journal[i].

About Abilify Maintena (aripiprazole)

Abilify Maintena (aripiprazole) for extended-release injectable suspension is in the U.S. indicated for the treatment of schizophrenia. Efficacy was demonstrated in a placebo-controlled, randomized-withdrawal maintenance trial in patients with schizophrenia. It is the first and only once-monthly injection of a dopamine D_2 partial agonist and was approved by the U.S. Food and Drug Administration (FDA) on 28 February 2013[ii, iii] and by the European Commission on 21 November 2013. In Europe, Abilify Maintena is indicated for maintenance treatment of schizophrenia in adult patients stabilised with oral aripoprazole.

Abilify Maintena, an atypical antipsychotic, is an IM depot formulation of aripiprazole. It is a sterile lyophilized powder that, when reconstituted with sterile water for injection, forms an injectable suspension that can be administered monthly. After an initial injection of Abilify Maintena along with an overlapping 14-day dosing of oral antipsychotic treatment, subsequent injections of Abilify Maintena provide uninterrupted medication coverage for 30 days at a time. It provides a treatment option to address one of the most important considerations in the management of schizophrenia – reducing the risk of relapse, or the re-emergence of worsening of symptoms[iii]. Depot formulations of antipsychotic

agents provide patients with concentrations of active drug that remain at a therapeutic range for an extended period of time[iii], [iv]. Abilify Maintena became available for prescribing in the U.S. on 18 March 2013.

About Schizophrenia

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 life-long treatment to mitigate symptoms. It has been estimated that schizophrenia affects approximately 1% of the adult population in the U.S., and approximately 24 million people worldwide[v, vi]. In the U.S., there are approximately 2.4 million adults with schizophrenia, prevalent equally in both genders[vii, viii]. While there is no cure for the disease, symptoms and risk of relapse—the re-emergence or worsening of psychotic symptoms[ix] – can be managed in most patients with appropriate antipsychotic treatment.

IMPORTANT SAFETY INFORMATION for ABILIFY MAINTENA® (aripiprazole) for extended-release injectable suspension

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk (1.6 to 1.7 times) of death compared to placebo (4.5% vs. 2.6%, respectively). Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. ABILIFY MAINTENA (aripiprazole) is not approved for the treatment of patients with dementia-related psychosis.

Contraindication: Known hypersensitivity reaction to aripiprazole. Reactions have ranged from pruritus/urticaria to anaphylaxis.

Cerebrovascular Adverse Events, Including Stroke: Increased incidence of cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, have been reported in clinical trials of elderly patients with dementia-related psychosis treated with oral aripiprazole.

Neuroleptic Malignant Syndrome (NMS): A potentially fatal symptom complex sometimes referred to as NMS may occur with administration of antipsychotic drugs, including ABILIFY MAINTENA. Rare cases of NMS occurred during aripiprazole treatment. Signs and symptoms of NMS include hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (e.g., irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other

drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available.

Tardive Dyskinesia (TD): The risk of developing TD (a syndrome of abnormal, involuntary movements) and the potential for it to become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic increase. The syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. Prescribing should be consistent with the need to minimize TD. There is no known treatment for established TD, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that include:

- **Hyperglycemia/Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis, coma, or death, has been reported in patients treated with atypical antipsychotics including aripiprazole. Patients with diabetes should be regularly monitored for worsening of glucose control; those with risk factors for diabetes should undergo baseline and periodic fasting blood glucose testing. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.
- **Dyslipidemia:** Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics. There were no significant differences between aripiprazole- and placebo-treated patients in the proportion with changes from normal to clinically significant levels for fasting/non-fasting total cholesterol, fasting triglycerides, fasting low-density lipoproteins (LDLs), and fasting/non-fasting high-density lipoproteins (HDLs).
- **Weight Gain:** Weight gain has been observed. Clinical monitoring of weight is recommended.

Orthostatic Hypotension: Aripiprazole may cause orthostatic hypotension. ABILIFY MAINTENA (aripiprazole) should be used with caution in patients with known cardiovascular disease, cerebrovascular disease, or conditions which would predispose them to hypotension.

Leukopenia, Neutropenia, and Agranulocytosis: Leukopenia, neutropenia, and agranulocytosis have been reported. Patients with a history of clinically significant low white blood cell (WBC) count or drug-induced leukopenia/neutropenia should have their complete blood count monitored frequently during the first few months of therapy while receiving ABILIFY MAINTENA. In such patients, consider discontinuation of ABILIFY MAINTENA at the first sign of a clinically significant decline in WBC count in the absence of other causative factors.

Seizures/Convulsions: ABILIFY MAINTENA should be used with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

Potential for Cognitive and Motor Impairment: ABILIFY MAINTENA (aripiprazole) may impair judgment, thinking, or motor skills. Instruct patients to avoid operating hazardous machinery including automobiles until they are certain ABILIFY MAINTENA does not affect them adversely.

Body Temperature Regulation: Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Advise patients regarding appropriate care in avoiding overheating and dehydration. Appropriate care is advised for patients who may exercise strenuously, may be exposed to extreme heat, receive concomitant medication with anticholinergic activity, or are subject to dehydration.

Dysphagia: Esophageal dysmotility and aspiration have been associated with ABILIFY MAINTENA; use caution in patients at risk for aspiration pneumonia.

Alcohol: Advise patients to avoid alcohol while taking ABILIFY MAINTENA.

Concomitant Medication: Dosage adjustments are recommended in patients who are CYP2D6 poor metabolizers and in patients taking concomitant CYP3A4 inhibitors or CYP2D6 inhibitors for greater than 14 days. If the CYP3A4 inhibitor or CYP2D6 inhibitor is withdrawn, the ABILIFY MAINTENA dosage may need to be increased. Avoid the concomitant use of CYP3A4 inducers with ABILIFY MAINTENA for greater than 14 days because the blood levels of aripiprazole are decreased and may be below the effective levels. Dosage adjustments are not recommended for patients with concomitant use of CYP3A4 inhibitors, CYP2D6 inhibitors or CYP3A4 inducers for less than 14 days.

Most commonly observed adverse reaction: The safety profile of ABILIFY MAINTENA is expected to be similar to that of oral aripiprazole. In patients who tolerated and responded to oral aripiprazole and single-blind ABILIFY MAINTENA and were then randomized to receive ABILIFY MAINTENA or placebo injections, the incidence of adverse reactions was similar between the two treatment groups. The adverse reaction ≥ 5% incidence and at least twice the rate of placebo for oral aripiprazole vs. placebo, respectively, was:

- Akathisia (8% vs. 4%) in adult patients with schizophrenia.

Injection Site Reactions: In the open-label, stabilization phase of a study with ABILIFY MAINTENA in patients with schizophrenia, the percent of patients reporting any injection site- related adverse reaction was 6.3% for ABILIFY MAINTENA-treated patients.

Dystonia is a class effect of antipsychotic drugs. Symptoms of dystonia may occur in susceptible individuals during the first days of treatment and at low doses.

Pregnancy/Nursing: Based on animal data, may cause fetal harm. ABILIFY MAINTENA (aripiprazole) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Aripiprazole is excreted in human breast milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Please see accompanying FULL PRESCRIBING INFORMATION, including Boxed WARNING, for ABILIFY MAINTENA.

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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 America Pharmaceutical, Inc.

Otsuka America Pharmaceutical, Inc. (OAPI) is an innovative, fast-growing healthcare company that commercializes Otsuka-discovered and in-licensed products in the U.S. With a strong focus on neuroscience, oncology, cardio-renal and medical devices, OAPI is dedicated to improving the health and quality of human life. For more information, visit www.otsuka-us.com.

OAPI is a subsidiary of Otsuka America, Inc. (OAI), a holding company established in the U.S. in 1989. OAI is wholly owned by Otsuka Pharmaceutical Co., Ltd. The Otsuka Group employs approximately 42,000 people globally and its products are available in more than 80 countries worldwide. Otsuka welcomes you to visit its global website at https://www.otsuka.co.jp/en/.

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 DKK 15.3 billion in 2013 (EUR 2.0 billion; USD 2.7 billion).

Lundbeck's shares are listed on the stock exchange in Copenhagen under the symbol "LUN". Lundbeck has a sponsored Level 1 ADR program listed in the US (OTC) under the symbol "HLUYY". For additional information, we encourage you to visit our corporate site www.lundbeck.com.

Safe Harbor/Forward-Looking Statements

The above information contains forward-looking statements that provide our expectations or forecasts of future events such as new product introductions, product approvals and financial performance.

Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations and it may cause any or all of our forward-looking statements here or in other publications to be wrong. Factors that may affect future results include interest rate and currency exchange rate fluctuations, delay or failure of development projects, production problems, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Lundbeck's products, introduction of competing products, Lundbeck's ability to successfully market both new and existing products, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws and related interpretation thereof, and unexpected growth in costs and expenses.

Certain assumptions made by Lundbeck are required by Danish Securities Law for full disclosure of material corporate information. Some assumptions, including assumptions relating to sales associated with product that is prescribed for unapproved uses, are made taking into account past performances of other similar drugs for similar disease states or past performance of the same drug in other regions where the product is currently marketed. It is important to note that although physicians may, as part of their freedom to practice medicine in the US, prescribe approved drugs for any use they deem appropriate, including unapproved uses, at Lundbeck, promotion of unapproved uses is strictly prohibited.

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[i] Data on file

[ii] U.S. Food and Drug Administration (FDA). FDA Approved Drug Products: All approvals February 2013. Available at: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.MonthlyApprovalsAll.

[iii] Prescribing Information. ABILIFY MAINTENA™ (aripiprazole) for extended-release injectable suspension, for intramuscular use. February 2013.

[iv] Kane JM, Sanchez R, Perry PP, et al. Aripiprazole intramuscular depot as maintenance treatment in patients with schizophrenia: a 52-week, multicenter, randomized, double- blind, placebo-controlled study. Journal of Clinical Psychiatry. 2012; 73(5): 617-624.

[v] National Institute of Mental Health (NIMH). Health Topics: Statistics. Available at http://www.nimh.nih.gov/statistics/1SCHIZ.shtml. Accessed May 14, 2013.

[vi] World Health Organization (WHO). Schizophrenia Fact Sheet. 2010. Available at http://www.who.int/mental_health/management/schizophrenia/en/. Accessed May 14, 2013.

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[viii] Regier, Darrel et al. The de Facto US Mental and Addictive Disorder Service System. Archives of General Psychiatry. 1993; 50: 85-94.

[ix] Almond, S et al. Relapse in schizophrenia: costs, clinical outcomes and quality of life. British Journal of Psychiatry, 2004; 184: 346-351.