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For Immediate Release

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**U.S. FDA APPROVES THE LABELING UPDATE OF ABILIFY MAINTENA[®]
(ARIPIPRAZOLE) FOR EXTENDED-RELEASE INJECTABLE SUSPENSION TO
DESCRIBE NEW CLINICAL DATA FOR THE TREATMENT OF ACUTELY RELAPSED
ADULTS WITH SCHIZOPHRENIA**

Otsuka Pharmaceutical Co., Ltd., a wholly-owned subsidiary of Otsuka Holdings Co. Ltd., and H. Lundbeck A/S today announced that the U.S. Food and Drug Administration (FDA) approved an expansion in the label of Abilify Maintena[®] (aripiprazole) for extended-release injectable suspension to include the treatment of acutely relapsed adults with schizophrenia.

Tokyo, Japan and Valby, Denmark – December 5, 2014 – Otsuka Pharmaceutical Co., Ltd. (Otsuka) and H. Lundbeck A/S (Lundbeck) announced that the U.S. Food and Drug Administration (FDA) approved the labeling update of Abilify Maintena[®] (aripiprazole) for extended-release injectable suspension. The approval was based on results from a controlled clinical study of acutely relapsed adults with schizophrenia. Efficacy was demonstrated in a 12-week randomized, double-blind, placebo-controlled study, which showed treatment with Abilify Maintena (with concomitant oral aripiprazole for the first two weeks) significantly improved symptoms with an acceptable safety and tolerability profile in adult patients experiencing an acute relapse of schizophrenia.¹ These data were published in the November print edition of *The Journal of Clinical Psychiatry*.²

Abilify Maintena, an atypical antipsychotic, was first approved by the FDA in February 2013 for intramuscular (gluteal) use for the treatment of schizophrenia. Efficacy was demonstrated in a placebo-controlled, randomized withdrawal maintenance trial in adult patients with schizophrenia, and additional support for efficacy was derived from oral aripiprazole trials.^{1,3}

“An acute exacerbation of psychotic symptoms, also referred to as disease relapse, is a key consideration in the management of schizophrenia, and can occur when a patient no longer responds to or stops taking antipsychotic medication,”¹ said study investigator John M. Kane, M.D., Chairman of Psychiatry, The Zucker Hillside Hospital, and Vice President, Behavioral Health Services, North Shore-LIJ Health System. “These

data – and the updated product labeling – confirm the utility of Abilify Maintena in acutely relapsed adult patients, giving physicians an option to consider for both the initial and ongoing treatment of patients with schizophrenia.”

About Abilify Maintena[®] (aripiprazole)

Abilify Maintena (aripiprazole once-monthly) is the first and only once-monthly injection of a dopamine D₂ partial agonist. It is available in the U.S. for the treatment of schizophrenia and in a number of European countries for maintenance treatment of schizophrenia in adult patients stabilized with oral aripiprazole. In Canada it is available for the maintenance treatment of schizophrenia in stabilized adult patients and in Australia for maintenance of clinical improvement in the treatment of schizophrenia.

Abilify Maintena, an atypical antipsychotic, is an intramuscular 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. Depot formulations of antipsychotic agents provide patients with concentrations of active drug that remain at a therapeutic range for an extended period of time.^{2,4}

References:

1. Prescribing Information. ABILIFY MAINTENA[®] (aripiprazole) for extended-release injectable suspension, for intramuscular use. December 2014.
2. Kane J., et al. Aripiprazole Once-Monthly in the Acute Treatment of Schizophrenia: Findings From a 12-Week, Randomized, Double-Blind, Placebo-Controlled Study. *Journal of Clinical Psychiatry*. 2014;75 (11): 1254–1260.
3. Drug Approval Reports. U.S. Food and Drug Administration (FDA). 2013. Available at: <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.MonthlyApprovalsAll>. Accessed November 11, 2014.
4. Kane J., 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: 617-624.