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For Immediate Release

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ABILIFY MAINTENA® (aripiprazole) for Extended-Release Injectable Suspension Approved by U.S. FDA for Maintenance Monotherapy Treatment of Bipolar I Disorder

- First FDA approved, once-monthly, long-acting injectable for the maintenance monotherapy treatment of bipolar I disorder in adults[*1, *2]
- New indication for ABILIFY MAINTENA is based on studies evaluating efficacy and safety in adult patients with bipolar I disorder[*1]

Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S announced ABILIFY MAINTENA® (aripiprazole) for extended-release injectable suspension was approved by the U.S. Food and Drug Administration for the maintenance monotherapy treatment of bipolar I disorder (BP-I) in adults.[*1]

ABILIFY MAINTENA is a once-monthly injectable formulation for intramuscular use created by Otsuka and has been co-developed and co-commercialized with Lundbeck. Based on Phase 3 study data, ABILIFY MAINTENA delayed the time to recurrence of any mood episode in adult patients experiencing a manic episode at screening compared to placebo.[*1]

"Bipolar I disorder is a recurrent chronic mental illness. ABILIFY MAINTENA provides healthcare professionals (HCPs) a new treatment option for their patients who have established tolerability with oral aripiprazole," said Joseph Calabrese, MD, Director of the Mood Disorders Program at University Hospitals Cleveland Medical Center, and Professor of Psychiatry at Case Western Reserve University School of Medicine. "Receiving ABILIFY MAINTENA each month as prescribed and administered by a HCP, provides patients an opportunity to be free from taking their daily antipsychotic for bipolar I disorder; it is important to note that concomitant oral antipsychotic must be administered for 14 days after the first injection."

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at increased risk of death. ABILIFY MAINTENA is not approved for the treatment of patients with dementia-related psychosis. ABILIFY MAINTENA is contraindicated with a known hypersensitivity reaction to aripiprazole.

For more information about ABILIFY MAINTENA, please visit: https://www.abilifymaintena.com/.

About the Clinical Trial

The Phase 3 clinical trial supporting regulatory approval demonstrated the efficacy and safety of ABILIFY MAINTENA in the maintenance monotherapy treatment of BP-I. The study included patients who were experiencing a manic episode at trial entry and met DSM-IV-TR criteria for bipolar I disorder. In addition, patients had a history of at least one previous manic or mixed episode with manic symptoms of sufficient severity to require one of the following interventions:

hospitalization and/or treatment with a mood stabilizer, and/or treatment with an antipsychotic agent. The clinical trial was a 52-week, double-blind, placebo-controlled, randomized withdrawal trial in adults with BP-I aged 18 to 65 years, who were stabilized with ABILIFY MAINTENA prior to randomization.[*1] The primary endpoint demonstrated ABILIFY MAINTENA significantly delayed time to recurrence of any mood episode during a 52-week treatment study compared with placebo.[*1] The trial demonstrated significant differences between treatment groups in delaying time to recurrence of both manic and mixed episodes but no substantial difference in depressive mood episodes.[*1]

About ABILIFY MAINTENA® (aripiprazole)

ABILIFY MAINTENA (aripiprazole) for extended-release injectable suspension is an atypical antipsychotic for intramuscular use. It was created by Otsuka in Japan and has been co-developed and co-commercialized by the alliance between Otsuka and Lundbeck. ABILIFY MAINTENA was approved in the U.S. in 2013 for the treatment of adults with schizophrenia.[*1] ABILIFY MAINTENA is a sterile lyophilized powder that when reconstituted with sterile water for injection, forms a suspension that can be administered by injection once a month (the initial injection is accompanied by an overlapping 14-day dosing of oral antipsychotic treatment). Subsequent doses of ABILIFY MAINTENA provide uninterrupted medication coverage for up to 30 days.[*1] Depot formulations of antipsychotic agents provide patients with concentrations of active drug that remain at a therapeutic range for extended periods of time.[*1, *2]

The most commonly observed adverse reactions with ABILIFY MAINTENA in patients with schizophrenia (incidence of 5 percent or greater and aripiprazole incidence at least twice that for placebo) were increased weight, akathisia, injection site pain, and sedation.[*1]

About Bipolar I Disorder

BP-I is a chronic mental illness with a 12-month and lifetime prevalence of 1.5 percent and 2.1 percent, respectively.[*3, *4] People with BP-I experience one or more episodes of mania, and may have episodes of both mania and depression.[*3, *5]

REFERENCES:

*1. ABILIFY MAINTENA® (aripiprazole) 2017 full prescribing information.
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*3. Bipolar Disorder. National Alliance on Mental Illness website. https://www.nami.org/Learn-More/Mental-Health-Conditions/Bipolar-Disorder. Accessed September 27, 2016.
*4. Epidemiology of DSM-5 bipolar I disorder: Results from the national epidemiologic survey on alcohol and related conditions - III. Blanco C, Compton WM, Saha TD et al. J Psychiatr Res 84 (2017) 310-317.
*5. National Institute of Mental Health. Serious Mental Illness (SMI) Among U.S. Adults. https://www.nimh.nih.gov/health/statistics/prevalence/serious-mental-illness-smi-among-us-adults.shtml. Accessed June 10, 2017.