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Company Name	Otsuka Holdings Co., Ltd.
Name of Representative	Tatsuo Higuchi President and Representative Director, CEO
Code Number	4578, Prime market of the Tokyo Stock Exchange
Contact	Yuji Kogure Director, Investor Relations Department (Phone: +81-3-6361-7411)

FDA Approves Otsuka and Lundbeck's ABILIFY ASIMTUFII® (aripiprazole), the First, Two-month, Long-acting Injectable (LAI) for the Treatment of Schizophrenia or Maintenance Monotherapy Treatment of Bipolar I Disorder in Adults

Otsuka America Pharmaceutical, Inc. (Otsuka) and Lundbeck Pharmaceuticals LLC (Lundbeck) announce the U.S. Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for ABILIFY ASIMTUFII® (aripiprazole) extended-release injectable suspension for intramuscular use, a once -every-two-months injection for the treatment of schizophrenia in adults or for maintenance monotherapy treatment of bipolar I disorder in adults.

ABILIFY ASIMTUFII offers two months of sustained therapeutic concentrations with one dose. Each dose is provided in a single-chamber, prefilled syringe, and is administered by a healthcare professional to appropriate patients via intramuscular injection in the gluteal muscle. Long-acting injectables provide continuous delivery of antipsychotic medication and can maintain therapeutic plasma concentrations, which may help to maintain symptom control of schizophrenia and bipolar I disorder.

“We are pleased to offer this new treatment option for people living with schizophrenia or bipolar I disorder that may delay the time to relapse,” said John Kraus, M.D., Ph.D., executive vice president and chief medical officer at Otsuka. “This approval underscores Otsuka’s commitment to innovate and continuously evolve to meet the needs of the communities we serve.”

The efficacy of ABILIFY ASIMTUFII is based on the adequate and well-controlled studies of ABILIFY MAINTENA® (aripiprazole) in the treatment of schizophrenia or maintenance treatment of bipolar I disorder in adults. The aripiprazole concentrations of ABILIFY ASIMTUFII were explored in a pharmacokinetic bridging study which was a 32-week, open-label, multiple-dose, randomized, parallel-arm, multicenter study (N=266) in patients living with schizophrenia and bipolar I disorder. The once-every-two-months, long-acting injectable formulation in 960 mg and 720 mg prefilled syringes delivers sustained plasma concentrations similar to that demonstrated in studies with aripiprazole monohydrate once-monthly, long-acting injectable, resulting in similar sustained efficacy.

“This approval is important news for patients, families, and healthcare providers. We hope that the use of ABILIFY ASIMTUFII in treatment plans will have a positive impact on those living with schizophrenia or bipolar I disorder,” said Johan Luthman, executive vice president, R&D, Lundbeck. “We are grateful to the patients and researchers who made this major milestone possible.”

About Schizophrenia

Schizophrenia is a severely debilitating mental illness characterized by delusions, hallucinations, and disordered cognition. Based on a systematic review of global data, the prevalence of schizophrenia in 2019 was estimated to be approximately 0.3% and did not vary

widely across countries or regions. The worldwide lifetime prevalence of the disease has been estimated to be approximately 0.9% across diverse geographic, cultural, and socioeconomic categories. The course of schizophrenia is typically characterized by acute episodes of psychotic behaviors occurring at varying intervals between periods of relative symptomatic stability.

About Bipolar I Disorder

Bipolar I disorder is a recurrent, lifelong mood disorder with a variable course that results in functional and cognitive impairment and a reduction in quality of life that affects 0.6% of the population. The course of bipolar I disorder is characterized by recurrent manic and depressive episodes that may last weeks or months. Over 90% of people with bipolar disorder experience recurrences during their lifetimes.

Bipolar I disorder often requires long-term pharmacologic treatment to delay time to recurrence. Long-acting injectables have the potential to provide continuous delivery of antipsychotic medication and can maintain therapeutic plasma concentrations, which may help address the variable nature of bipolar disorder.