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Otsuka and Lundbeck Announce U.S. FDA Acceptance of New Drug Application for Aripiprazole 2-month, Ready-to-Use, Long-acting Injectable to Treat Schizophrenia and Bipolar I Disorder in Adults

- *If approved, aripiprazole 2-month ready-to-use (RTU), long-acting injectable (LAI) would be the first 2-month, LAI antipsychotic indicated for both treatment of schizophrenia and the maintenance treatment of bipolar I disorder in U.S.*
- *Filing is supported by a 32-week bridging trial in which aripiprazole 2-month showed comparable effectiveness and consistent safety profile to aripiprazole 1-month.*
- *The FDA target date (PDUFA date) for completion of the review is April 27, 2023.*

PRINCETON, NJ and DEERFIELD, IL - September 13, 2022 - Otsuka America Pharmaceutical, Inc., (Otsuka) and H. Lundbeck A/S (Lundbeck) announce the U.S. Food and Drug Administration (FDA) acceptance of their New Drug Application (NDA) for aripiprazole 2-month, ready-to-use, long-acting injectable, a medication administered for the treatment of schizophrenia in adults and for maintenance monotherapy treatment of bipolar I disorder in adults.

Aripiprazole 2-month, ready-to-use, long-acting injectable is provided in a single-chamber-type, prefilled syringe. It is intended for dosing every two months via intramuscular injection in the gluteal muscle.

"This is an important milestone in our efforts to offer adult patients with schizophrenia or bipolar I disorder a new option designed to support treatment goals and offer greater flexibility. The trial results reinforce the long-standing efficacy and safety profile of the once-monthly aripiprazole long-acting injectable," said Johan Luthman, executive vice president, Lundbeck Research & Development.

The 2-month, ready-to-use, long-acting injectable of aripiprazole in 960 mg and 720 mg prefilled syringes will deliver sustained plasma concentrations similar to that demonstrated in studies with aripiprazole once-monthly long-acting injectable, resulting in consistent efficacy. Regulatory approval would be based on a multiple-dose, randomized, parallel-arm, clinical trial to assess safety, tolerability, and pharmacokinetics in adults with schizophrenia or bipolar I disorder.

"Stability is critical for patients with schizophrenia and bipolar I – which means delaying time to relapse or recurrence and supporting their role as functioning members of their community," said Robert McQuade, PhD, executive vice

president and chief strategy officer, Otsuka Pharmaceutical Development & Commercialization, Inc. "As we continue our efforts to bring aripiprazole 2-month to market, we remain committed to our patients and confident that the favorable safety and tolerability profile will be clearly visible."

About aripiprazole 2-month, ready-to-use long-acting injectable

Aripiprazole 2-month, ready-to-use long-acting injectable is provided in a single-chamber-type, prefilled syringe (PFS) that does not require reconstitution, intended for dosing every two months via intramuscular (IM) injection in the gluteal muscle in the same patient populations as indicated for once-monthly ABILIFY MAINTENA® (aripiprazole).

Results from the pivotal trial 031-201-00181, that enrolled 266 patients, demonstrated that aripiprazole ready-to-use LAI 960 mg met the primary endpoint criteria establishing similarity of aripiprazole plasma concentrations and thus comparable effectiveness to aripiprazole once-monthly 400 mg over a two-month dosing interval.

Multiple-dose administrations of aripiprazole 2-month, RTU, LAI 960 mg were generally safe and well tolerated in subjects with schizophrenia or bipolar I disorder and did not show any new safety concerns compared to aripiprazole once-monthly 400 mg.