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Otsuka Applies for the Additional Indication in Japan of Bipolar Disorder for ABILIFY MAINTENA for Suspended Release Injectable Suspension

Otsuka Pharmaceutical Co., Ltd. announces that it has filed an application in Japan for the additional indication of suppression of recurrence and relapse of mood episodes in bipolar disorder for ABILIFY MAINTENA (aripiprazole), a long-acting injectable suspension.

The application covers the 300 mg and 400 mg vials (for injection) and the 300 mg and 400 mg dual-chamber syringes.

ABILIFY MAINTENA is a depot preparation for intramuscular injection that provides uninterrupted medication coverage for up to 30 days. Otsuka Pharmaceutical created ABILFY MAINTENA, an atypical antipsychotic, which first received regulatory approval in 2013 in the U.S. and E.U. for the treatment of adult schizophrenia. In 2015, it was approved in Japan for the same indication. In the United States and Canada, the indication as maintenance therapy for adult bipolar I maintenance therapy was added in 2017.