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For Immediate Release

Company name Otsuka Holdings Co., Ltd.

Representative Tatsuo Higuchi

President and Representative Director, CEO

Code number 4578 First Section, Tokyo Stock Exchange

Inquiries Yuji Kogure

Director, Investors Relations Department

Otsuka's ABILIFY MAINTENA approved for the additional indication of bipolar I disorder in Japan

Otsuka Pharmaceutical Co., Ltd. announces that it has received regulatory approval in Japan for the additional indication of suppression of recurrence and relapse of mood episodes in bipolar I disorder for ABILIFY MAINTENA (aripiprazole), a long-acting injectable suspension. The approved indication 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 administered monthly as a single injection.

Otsuka Pharmaceutical discovered 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 U.S. and Canada, the indication as maintenance therapy for adult bipolar I maintenance therapy was added in 2017.