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**For Immediate Release**


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# OTSUKA FILES FOR APPROVAL IN JAPAN FOR AN ADDITIONAL INDICATION FOR THE ANTIPSYCHOTIC ABILIFY: EXCITABILITY ASSOCIATED WITH JUVENILE AUTISM

Otsuka Pharmaceutical Co., Ltd., a wholly-owned subsidiary of Otsuka Holdings Co. Ltd., today announced that Otsuka Pharmaceutical Co., Ltd. has submitted an application for regulatory approval in Japan of the anti-psychotic drug ABILIFY (generic name is aripiprazole) for the additional indication of excitability associated with autistic disorder for juveniles from ages 6 through 17.

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- An application has been filed with regulatory authorities in Japan for the approval of an additional indication for the antipsychotic ABILIFY, which has been prescribed in Japan since 2006. The additional indication sought for ABILIFY is for excitability associated with autism in juveniles.
- The prevalence of autism in Japan is between 2 and 20 people per 10,000, and the total number of patients is reported as approximately 21,000. Few treatment options exist for the excitability that occurs in about 20% of people with autism and new treatment agents that can be safely used for it are eagerly awaited.
- ABILIFY received approval from the U.S. FDA in 2009 for use in patients with excitability associated with autism and in Japan three medical societies active in the field of autism specified the high medical need and expectation for the development of new medicines for autism.

***Tokyo, Japan – December 7, 2015 –*** Otsuka Pharmaceutical Co., Ltd. has submitted an application for regulatory approval in Japan of the anti-psychotic drug ABILIFY (generic name is aripiprazole) for the additional indication of excitability associated with autistic disorder for juveniles from ages 6 through 17. The proposed dosage form for the indication is ABILIFY Tablets, 1mg.