December 1, 2016

For Immediate Release

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FDA Accepts For Review A Supplemental New Drug Application To Expand Labeling Of Abilify Maintena® (aripiprazole) For The Treatment Of Bipolar I Disorder

Otsuka Pharmaceutical Co., Ltd., a wholly-owned subsidiary of Otsuka Holdings Co. Ltd., today announced the U.S. Food and Drug Administration (FDA) has determined that the supplemental New Drug Application (sNDA) for the expanded labeling of ABILIFY MAINTENA® for the maintenance treatment of bipolar I disorder in adult patients is sufficiently complete to permit a substantive review and is considered filed.

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- Application seeks to expand ABILIFY MAINTENA® label to include maintenance treatment for bipolar I disorder
- If the label expansion is approved, ABILIFY MAINTENA® would offer prescribers a once-monthly long-acting injectable treatment option in the maintenance treatment of bipolar I disorder in adults

Tokyo, Japan – December 1, 2016 – Otsuka Pharmaceutical Co., Ltd. (Otsuka) and Lundbeck announced the U.S. Food and Drug Administration (FDA) has determined that the supplemental New Drug Application (sNDA) for the expanded labeling of ABILIFY MAINTENA® for the maintenance treatment of bipolar I disorder in adult patients is sufficiently complete to permit a substantive review and is considered filed. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target date of July 28, 2017, to complete its review.