

For Immediate Release

September 5, 2018
Sawai Pharmaceutical Co., Ltd.

MHLW Approves New Indication for ARIPIPRAZOLE Tablets 3 mg / 6 mg / 12 mg / 24 mg [SAWAI] and ARIPIPRAZOLE Oral Solution 3 mg / 6mg / 12 mg Packet [SAWAI]

Osaka, Japan –September 5, 2018 – Sawai Pharmaceutical Co., Ltd. (Sawai, Head office: Osaka, Japan, President: Mitsuo Sawai) today received approval of partial change applications by the Ministry of Health, Labour and Welfare (MHLW) for ARIPIPRAZOLE Tablets 3 mg / 6 mg / 12 mg / 24 mg [SAWAI] and ARIPIPRAZOLE Oral Solution 3 mg / 6mg / 12 mg Packet [SAWAI]*.

* Brand products: ABILIFY® Tablets 1 mg / 3 mg / 6 mg / 12 mg and ABILIFY® Oral Solution 0.1 %

“Indications and Usage” and “Dosage and Administration” after approvals are as below;

<p>Indications and Usage (New approval is underlined)</p>	<ul style="list-style-type: none"> ● Schizophrenia ● <u>Improvement of manic episodes associated with bipolar disorder</u>
<p>Dosage and Administration (New approval is underlined)</p>	<ul style="list-style-type: none"> ● Schizophrenia The usual adult dosage for oral use is 6-12 mg (starting dose) and 6-24 mg (maintenance dose) of aripiprazole daily in one or two divided doses. The dosage may be adjusted according to the patient's age and symptoms, but should not exceed 30 mg per day. ● <u>Improvement of manic episodes associated with bipolar disorder</u> <u>The usual adult dosage for oral use is 12-24 mg of aripiprazole daily in one dose. The starting dosage is 24 mg, and may be adjusted according to the patient's age and symptoms, but should not exceed 30 mg per day.</u>

The following indications are not included with this approval.

- Depression / depressive state
- Irritability associated with autism spectrum disorder in pediatric patients

◆ Contact information ◆

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