For Immediate Release

March 6, 2019
Sawai Pharmaceutical Co., Ltd.

MHLW Approves New Indication for ARIPIPRAZOLE Tablets and Oral Solution

Osaka, Japan – March 6, 2019 – 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 and 12 mg [SAWAI], and ARIPIPRAZOLE Oral Solution 3 mg, 6 mg and 12 mg Packet [SAWAI]*.

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

"Indications and Usage" and "Dosage and Administration" after approvals are described below (New approval is underlined);

Indications and Usage

1. Schizophrenia
2. Improvement of manic episodes associated with bipolar disorder
3. Depression / depressive state (only in cases which are responding inadequately to existing treatment)

Dosage and Administration

1. 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.
2. Improvement of manic episodes associated with bipolar disorder
   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.
3. Depression / depressive state (only in cases which are responding inadequately to existing treatment)
   The usual adult dosage for oral use is 3 mg of aripiprazole daily in one dose. The dosage may be increased in increments of 3 mg a day based on the patient's age and symptoms. The maximum daily dose is 15 mg a day.

The following indication is not included with this approval:

- Irritability associated with autism spectrum disorder in pediatric patients

The products announced in this press release are not approved by the Food & Drug Administration for sale and distribution in the United States.

◆ Contact information ◆
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