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**MHLW Approves New Indication for ARIPIPRAZOLE Tablets 3 mg / 6 mg / 12 mg / 24 mg [SAWAI] and ARIPIPRAZOLE Oral Solution 3 mg / 6 mg / 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 approval are listed below:

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| **Indications and Usage****(New approval is underlined)** | * Schizophrenia
* Improvement of manic episodes associated with bipolar disorder
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| **Dosage and Administration****(New approval is underlined)** | * 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.* 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. |

The following indications are not included with this approval.

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

**About Sawai**

Founded in 1929, Sawai Pharmaceutical Co., Ltd. has grown into one of the leading generics companies in Japan. Guided by its corporate philosophy, “Always Putting Patients First,” Sawai markets more than 700 high-quality generic products and reliably delivers them to patients throughout Japan. In 2017, Sawai acquired US-based Upsher-Smith Laboratories, LLC marking its first step in overseas expansion to become a globally recognized generic pharmaceutical company. For more information, visit: <https://www.sawai.co.jp/en/>.

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

**For further information please contact:**

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