



## MHLW Approves New Indication for OSELTAMIVIR Capsules 75mg [SAWAI] / Dry Syrup 3% [SAWAI]

Osaka, Japan – June 6, 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 OSELTAMIVIR Capsules 75mg [SAWAI] and OSELTAMIVIR Dry Syrup 3% [SAWAI]\*.

This approval expands the indication of OSELTAMIVIR Capsules 75mg [SAWAI] and OSELTAMIVIR Dry Syrup 3% [SAWAI] to include the same uses as their brand equivalents.

\* Brand products: TAMIFLU® Capsules 75mg and Dry Syrup 3%

“Indications and Usage” and “Dosage and Administration” after approval are listed below:

### (1) OSELTAMIVIR Capsules 75mg [SAWAI]

<b>Indications and Usage (New approval is underlined)</b>	Treatment <u>or prophylaxis</u> of influenza type A or B virus infection
<b>Dosage and Administration (New approval is underlined)</b>	1. When used for treatment In general, adults and children weighing 37.5kg or more are orally administered 75mg as oseltamivir twice a day for 5 days. 2. <u>When used for prophylaxis</u> (1) <u>Adults</u> <u>In general, 75mg as oseltamivir is administered orally once a day for 7 to 10 days.</u> (2) <u>Children weighing 37.5kg or more</u> <u>In general, 75mg as oseltamivir is administered orally once a day for 10 days.</u>

(2) OSELTAMIVIR Dry Syrup 3% [SAWAI]

<b>Indications and Usage</b> <b>(New approval is underlined)</b>	Treatment <u>or prophylaxis</u> of influenza type A or B virus infection
<b>Dosage and Administration</b> <b>(New approval is underlined)</b>	1. When used for treatment (1) Adults In general, 75mg as oseltamivir is suspended before use and administered orally twice a day for 5 days. (2) Children In general, the dosage below is suspended before use and administered orally twice a day for 5 days. However, the maximum dose per administration is 75mg as oseltamivir. Children and young children: 2mg/kg as oseltamivir (66.7 mg/kg as Dry Syrup) <u>Neonates and infants: 3mg/kg as oseltamivir (100mg/kg as Dry Syrup)</u> 2. <u>When used for prophylaxis</u> (1) <u>Adults</u> <u>In general, 75mg as oseltamivir is suspended before use and administered orally once a day for 7 to 10 days.</u> (2) <u>Children</u> <u>In general, the dosage below is suspended before use and administered orally once a day for 10 days. However, the maximum dose per administration is 75mg as oseltamivir.</u> <u>Children and young children: 2mg/kg as oseltamivir (66.7 mg/kg as Dry Syrup)</u>

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

**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, "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/>.

**For further information please contact:**

PR/IR group, [pr@sawai.co.jp](mailto:pr@sawai.co.jp)