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MHLW Approves New Indication for LEVOFOLINATE I.V. Infusion

Osaka, Japan –November 21, 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 LEVOFOLINATE I.V. Infusion 25 mg [SAWAI] and 100 mg [SAWAI]*.

This approval expands the indication of LEVOFOLINATE I.V. Infusion 25 mg [SAWAI] and 100 mg [SAWAI] to include the same uses as their brand equivalents.

* Brand products: ISOVORIN® I.V. Infusion 25 mg and 100 mg

"Indications and Usage" and "Dosage and Administration" after approval are listed below:

Indications and Usage (New approval is underlined)	1. Levofolinate and 5-Fluorouracil therapy Enhancing the effect of 5-fluorouracil for the treatment of gastric cancer (which is inoperable or recurrent) and colorectal cancer 2. Levofolinate and 5-Fluorouracil continuous intravenous combination therapy Enhancing the effect of 5-fluorouracil for the treatment of colorectal cancer, <u>small intestine cancer</u> and pancreatic cancer not amenable to curative resection
Dosage and Administration (New approval is underlined)	1. Levofolinate and 5-Fluorouracil therapy In general, for adults, 250 mg/m^2 (body surface) as levofolinate is administered by intravenous drip infusion at one time over a period of 2 hours. 600 mg/m^2 (body surface) as 5-fluorouracil is administered by bolus intravenous injection at one time within 3 minutes, 1 hour after beginning the levofolinate infusion. Repeat 6 times during 1 week, followed by a 2 week break. This is 1 cycle. 2. Levofolinate and 5-Fluorouracil continuous intravenous combination therapy for colorectal cancer (1) In general, for adults, 100 mg/m^2 (body surface) as levofolinate is administered by intravenous drip infusion at one time over a period of 2 hours. Immediately followed by 400 mg/m^2 (body surface) as 5-fluorouracil is administered by intravenous injection at one time and 600 mg/m^2 (body surface) as 5-fluorouracil is administered by continuous intravenous injection at one time over a period of 22 hours. This is continued for 2

	days and repeated every 2 weeks. (2) In general, for adults, 250 mg/m^2 (body surface) as levofolinate is administered by intravenous drip infusion at one time over a period of 2 hours. Immediately followed by 2600 mg/m^2 (body surface) as 5-fluorouracil is administered by continuous intravenous injection at one time over a period of 24 hours. Repeat 6 times duringy 1 week, followed by a 2 week break. This is 1 cycle. (3) In general, for adults, 200 mg/m^2 (body surface) as levofolinate is administered by intravenous drip infusion at one time over a period of 2 hours. Immediately followed by 400 mg/m^2 (body surface) as 5-fluorouracil is administered by intravenous injection at one time and 2400 to 3000 mg/m^2 (body surface) as 5-fluorouracil is administered by continuous intravenous injection at one time over a period of 46 hours. This is continued every 2 weeks. 3. Levofolinate and 5-Fluorouracil continuous intravenous combination therapy for small intestine cancer and pancreatic cancer not amenable to curative resection In general, for adults, 200 mg/m^2 (body surface) as levofolinate is administered by intravenous drip infusion at one time over a period of 2 hours. Immediately followed by 400 mg/m^2 (body surface) as 5-fluorouracil is administered by intravenous injection at one time and 2400 mg/m^2 (body surface) as 5-fluorouracil is administered by continuous intravenous injection at one time over a period of 46 hours. This is continued every 2 weeks.

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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