

This material is an English translation of the press release announced on June 29, 2020 in Japanese, and the Japanese release is given priority about the content and the interpretation.

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June 29, 2020

**Notification of approval for manufacturing and marketing approval of the additional indications of cancer pain relief for opioid analgesic naïve patients of Fentos® Tape (Transdermal, pain management patch, Development code: HFT-290) in Japan**

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu city, Saga Prefecture, Japan; President and CEO: Kazuhide Nakatomi, hereinafter referred to as “Hisamitsu Pharmaceutical”) announces that it has obtained approval of the additional indications of cancer pain relief for opioid analgesic naïve patients for Fentos® Tape, transdermal, pain management patch (Development code: HFT-290, generic name: fentanyl citrate, hereinafter referred to as “the product”) in Japan as of today.

Hisamitsu Pharmaceutical conducted a clinical study in opioid analgesic naïve cancer pain patients of the product (starting dose at 0.5mg) and confirmed the efficacy and safety of the product. With this approval, the product became the first strong opioid patch in Japan that can be used in opioid analgesic naïve cancer pain patients. Hisamitsu Pharmaceutical expects the product to be a new option for treating cancer pain.

Hisamitsu Pharmaceutical obtained an approval for the product in April 2010 with indication for pain relief in various cancers that accompany moderate to severe pain and obtained an approval for the product in June 2014 for the addition of indication for chronic pain. In addition, Hisamitsu Pharmaceutical obtained approval for the product in July 2018 for the addition of a new dose of 0.5mg.

Additionally, Hisamitsu Pharmaceutical has jointly carried out product distribution and activities for the provision and collection of information (1 brand, 2 channels) with Kyowa Kirin Co., Ltd., hereinafter referred to as “Kyowa Kirin”(Head office: Chiyoda-ku, Tokyo, Japan; President: Masashi Miyamoto) since June 2010.

Hisamitsu Pharmaceutical and Kyowa Kirin will contribute continually to further improving the quality of life of patients who suffer from cancer pain and chronic pain by providing proper medical information of the product.