

This material is an English translation of the press release announced on August 25, 2021 in Japanese, and the Japanese release is given priority about the content and the interpretation.

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August 25, 2021

**Notification of approval for manufacturing and marketing approval of  
the additional indications of cancer pain relief for pediatric patients of  
FENTOS® Tapes (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 pediatric patients for FENTOS® Tapes, 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 pediatric cancer pain patients (aged 2 to 19 years old) and confirmed the efficacy and safety of the product. With this approval, the product became the first strong opioid patch in Japan with an indication for pediatric cancer pain. 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 in June 2014 for the additional indication of pain relief in chronic pain, and obtained an approval in July 2018 for the additional new dose of 0.5mg. In addition, Hisamitsu Pharmaceutical obtained approval in June 2020 for the additional indication of cancer pain relief for opioid analgesic naïve patients.

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. (Head office: Chiyoda-ku, Tokyo, Japan; President and CEO: Masashi Miyamoto) since June 2010.

Hisamitsu Pharmaceutical will contribute to improving the quality of life for pediatric cancer pain patients by providing proper medical information of the product.