

This material is an English translation of the press release announced on September 10, 2020 in Japanese, and the Japanese release is given priority about the content and the interpretation.

September 10, 2020

Notification of application for manufacturing and marketing approval of the additional indications of cancer pain relief for pediatric 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 Hisamitsu Pharmaceutical has submitted a new drug application for the additional indications of cancer pain relief for pediatric 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 pediatric cancer pain patients (aged 2 to 19 years old) and confirmed the efficacy and safety of the product.

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., hereinafter referred to as “Kyowa Kirin”(Head office: Chiyoda-ku, Tokyo, Japan; President and CEO: Masashi Miyamoto) since June 2010.

With this additional indication, Hisamitsu Pharmaceutical expects that the product will be a new treatment option for pediatric cancer pain patients, and will contribute to improving their quality of life.

Hisamitsu Pharmaceutical aims to obtain a manufacturing and marketing approval of the additional indications during FY2021.