

This material is an English translation of the press release announced on August 29, 2019 in Japanese, and the Japanese release is given priority about the content and the interpretation.

August 29, 2019

Notification of application for manufacturing and marketing approval of the additional indications of opioid analgesic naïve cancer pain relief 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 been submitted a new drug application for the additional indications of opioid analgesic naïve cancer pain relief for the transdermal, pain management patch FENTOS®TAPE (Development code: HFT-290, generic name: fentanyl citrate, hereinafter referred to as “the product”).

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.

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

Hisamitsu Pharmaceutical aims to obtain a manufacturing and marketing approval of the additional indications during FY2020.