This material is an English translation of the press release announced on July 2, 2018 in Japanese, and the Japanese release is given priority about the content and the interpretation.

July 2, 2018

Notification of approval of supplemental new drug application (NDA)
for the addition of a new 0.5mg dose of the transdermal,
pain management patch FENTOS® TAPE (development code: HFT-290)

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu city, Saga prefecture, Japan; Chairman and CEO: Hirotaka Nakatomi, hereinafter referred to as Hisamitsu) announced today that it approved the supplemental new drug application (NDA) for the addition of a new 0.5mg dose of the transdermal, pain management patch FENTOS® TAPE (development code: HFT-290, hereinafter referred to as the product) .

Hisamitsu conducted a clinical study on the 0.5mg dose of the product in patients with cancer pain and confirmed the efficacy and safety of the product. And Hisamitsu expects that the 0.5mg dose of the product in patients with cancer pain and chronic pain enables more careful dose adjustment in dose selection at the time of switching from low dose other opioid analgesic and in dose increase or decrease.

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

Hisamitsu contribute to improvement of a quality of life in patients with cancer pain and chronic pain.