This material is an English translation of the press release announced on August 31, 2017 in Japanese, and the Japanese release is given priority about the content and the interpretation.

August 31, 2017

Notification of submission of supplemental new drug application (NDA)
for the addition of a new 0.5mg dose of the transdermal,
long-acting pain relief 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 submitted the supplemental new drug application (NDA) for the addition of a new 0.5mg dose of the transdermal, long-acting pain relief 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 chronic pain and confirmed the efficacy and safety of the product. And Hisamitsu expects that the 0.5mg dose of the product 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: Nobuo Hanai) since June 2010.

Hisamitsu aims to obtain an approval of the additional new 0.5mg dose in FY 2018.