This material is an English translation of the press release announced on December 14, 2018 in Japanese, and the Japanese release is given priority about the content and the interpretation.

December 14, 2018

Notification of the results of Phase III clinical study in opioid analgesic naïve patients 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") announces that the transdermal, pain management patch FENTOS®TAPE (development code: HFT-290, hereinafter referred to as the product) achieved the primary endpoint of the Phase III clinical study in Japan.

In this study, the efficacy and safety of administration of the product (starting dose at 0.5mg) was confirmed in opioid analgesic naïve cancer pain patients. As a result, the efficacy of product was confirmed in the primary endpoint (efficacy rate using the degree of improvement in analgesic). In addition, no adverse reactions were observed that could cause major concerns in development.

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. In addition, Hisamitsu obtained approval for the product in July 2018 for the addition of a new dose of 0.5mg.

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 aims to apply for partial changes in approval of additional indications for opioid analgesic naïve patients during FY2019.