Notification of submission of supplemental new drug application (NDA) for the addition of indication for chronic pain on the transdermal, long-acting cancer pain relief patch FENTOS® TAPE (development code: HFT-290)

Hisamitsu Pharmaceutical Co., Inc., (Head Office: Tosu city, Saga Prefecture, Japan; President and CEO: Hirotaka Nakatomi; hereinafter referred to as Hisamitsu) announced today that it submitted the supplemental new drug application (NDA) for the addition of indication for chronic pain on the transdermal, long-acting cancer pain relief patch FENTOS® TAPE (development code: HFT-290).

Hisamitsu conducted a clinical study of once daily administration of the product in patients with moderate to severe chronic pain and confirmed the efficacy and safety of the product.

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 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 indication of the product for chronic pain in FY 2014.