

News release

Kyowa Kirin Announces an Partial Change Approval Application of FENTOS®TAPE (Code: HFT-290) Submission by Hisamitsu Pharmaceutical in Japan

Tokyo, Japan, August 29, 2019 --- Kyowa Kirin Co., Ltd., (Kyowa Kirin, President and CEO: Masashi Miyamoto) today announced that Hisamitsu Pharmaceutical Co., Inc. (Hisamitsu Pharmaceutical, President and CEO: Kazuhide Nakatomi) has 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, “the product”) in Japan.

Hisamitsu Pharmaceutical has conducted the clinical study in opioid analgesic naïve cancer pain patients with the product (starting dose at 0.5mg) and confirmed the efficacy and safety of the product.

The product was granted the approval for the treatment of pain relief in various cancers that accompany moderate to severe pain in April 2010 and the additional indication approval for chronic pain in June 2014. In addition, the product was granted the additional approval of a new dose of 0.5mg in July 2018.

Kyowa Kirin and Hisamitsu Pharmaceutical have jointly carried out product distribution and activities of the provision and collection of information (1 brand, 2 channels) since June 2010. Through providing appropriate information of the product with Hisamitsu Pharmaceutical, Kyowa Kirin looks forward to giving further contribution to improve quality of life in patients suffering from cancer pain or chronic pain.

Hisamitsu Pharmaceutical expects to receive a manufacturing and marketing approval of the additional indications by February 2021.

The Kyowa Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.