

Announcement 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)

Tokyo, Japan, Aug. 31th, 2017 -- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and CEO: Nobuo Hanai, "Kyowa Hakko Kirin") announced today that Hisamitsu Pharmaceutical Co., Inc. (Tosu, Saga, President and CEO: Hirotaka Nakatomi, "Hisamitsu Pharmaceutical") 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 Pharmaceutical has confirmed the efficacy and safety of the 0.5 mg dose of the product in the clinical study for patients with cancer pain and submitted the supplemental NDA. The 0.5 mg dose of the product is expected to enable more precise adjustment than with existing dose selection in switching from other low dose opioid analgesic or in dosage changing of the product.

The product was developed as a transdermal patch of fentanyl citrate, a synthetic narcotic with significant analgesic effects, using Hisamitsu Pharmaceutical's Transdermal Drug Delivery System (TDDS). Hisamitsu Pharmaceutical received the marketing authorization in Japan of the product for pain relief in various cancers that accompany moderate-to-severe pain in Apr. 2010, and for moderate-to-severe chronic pain in June 2014.

Kyowa Hakko Kirin and Hisamitsu Pharmaceutical have been collaborating on the distribution, the provision and the information collecting of the product (one brand, two channels) since June 2010. Through providing appropriate information of the product, Kyowa Hakko Kirin and Hisamitsu Pharmaceutical would keep contributing to improve quality of life in patients with cancer pain or chronic pain.

The Kyowa Hakko 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.