

Kyowa Kirin Announces Partial Change Approval of FENTOS[®] Tapes in Japan

Tokyo, Japan, August 25, 2021 --Kyowa Kirin Co., Ltd. (TSE:4151, President and CEO: Masashi Miyamoto, "Kyowa Kirin") today announced that Hisamitsu Pharmaceutical Co., Inc. (President and CEO: Kazuhide Nakatomi, "Hisamitsu Pharmaceutical") has received a partial change approval for the additional indications of cancer pain relief for pediatric patients for FENTOS[®] Tapes, transdermal, pain management patch (Development code: HFT-290, generic name: fentanyl citrate, hereinafter referred to as "the product") in Japan as of today.

Hisamitsu Pharmaceutical, Kyowa Kirin's business partner on the product, conducted a clinical study in pediatric cancer pain patients (aged 2 to 19 years old) and confirmed the efficacy and safety of the product. Kyowa Kirin expects that the product, which is the first transdermal strong opioid patch with an indication for pediatric cancer pain in Japan, could be a new treatment option for pediatric cancer pain patients.

The product was first approved in April 2010 with indication for pain relief in various cancers that accompany moderate to severe pain, and later approved for the additional indications of pain relief in chronic pain in June 2014, the additional new dose of 0.5mg in July 2018 and cancer pain relief for opioid analgesic naïve patients in June 2020.

Kyowa Kirin and Hisamitsu Pharmaceutical have jointly carried out product distribution and activities for the provision and collection of information (1 brand, 2 channels) since June 2010. Under the collaboration with Hisamitsu Pharmaceutical, Kyowa Kirin continues to dedicate ourselves to improving the quality of life for patients suffering from pediatric cancer pain.

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.