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Hisamitsu Pharmaceutical Submits Application Seeking Approval for Additional Indication of Chronic Pain for Fentos® Tape, a Transdermal Long-Acting Cancer Pain Relief Patch

Tokyo, Japan, July 31, 2013 -- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and CEO: Nobuo Hanai, "Kyowa Hakko Kirin") announced that the Company was informed on July 31, 2013 by Hisamitsu Pharmaceutical Co., Inc. (Tosu, Saga, President and CEO: Hirotaka Nakatomi, "Hisamitsu Pharmaceutical") that it has been filed an application to Japan's Ministry of Health, Labour and Welfare (MHLW) seeking approval for additional indication of chronic pain* for Fentos® Tape (development code: HFT-290, "Fentos® Tape"), a transdermal long-acting cancer pain relief patch.

Fentos® Tape is a narcotic ethical (Rx) pharmaceutical product developed as a transdermal patch of fentanyl citrate, a synthetic narcotic that exhibits significant analgesic effects, using Hisamitsu Pharmaceutical's transdermal drug delivery system (TDDS). Kyowa Hakko Kirin and Hisamitsu Pharmaceutical have been collaborating on the distribution of this product and the provision and collection of information (one brand, two channels) since June 2010.

Hisamitsu Pharmaceutical made the application seeking approval based on the results of domestic clinical trials of HFT-290, which demonstrated its efficacy and safety for patients with moderate-to-severe chronic pain.

Kyowa Hakko Kirin will continue to market Fentos® Tape jointly with Hisamitsu Pharmaceutical. The companies hope that approval of the additional indication of chronic pain will contribute to improved quality of life in patients suffering from chronic pain.

ENDS

* Chronic pain

In the International Association for the Study of Pain, Chronic pain is defined as pain without apparent biological value that has persisted beyond the normal tissue healing time (usually taken to be 3 months).