Launch of Abstral[®] sublingual tablets for Cancer Pain Treatment in Japan

Tokyo, Japan, December 11, 2013 -- Kyowa Hakko Kirin Co., Ltd. (Tokyo; 4151 President and CEO: Nobuo Hanai; "Kyowa Hakko Kirin") and Hisamitsu Pharmaceutical Co., Inc. (Saga, Japan; 4530 President and CEO, Hirotaka Nakatomi; "Hisamitsu Pharmaceutical") announced today that they will launch Abstral® sublingual tablet 100μg, 200μg and 400μg (nonproprietary name: fentanyl citrate; referred to below as "Abstral®") in Japan December 12, 2013.

Abstral[®], which is to be administered sublingually, is a treatment for sudden pain (breakthrough pain) that occurs during chronic cancer pain management, and its major effect is pain relief due to prompt fentanyl absorption. The drug was listed on the National Health Insurance Drug Price List on November 19, 2013 after the manufacturing and marketing approval in Japan on September 20, 2013. The efficacy and safety of the drug were confirmed in the Clinical trials,

Kyowa Hakko Kirin and Hisamitsu Pharmaceutical had entered into a collaboration agreement to sale Abstral[®] jointly, and will collaborate on the distribution of this drug and the provision and collection of information (2 channels for 1 brand).

This drug was licensed from Orexo AB. (Uppsala, Sweden; President and CEO: Nikolaj Sørensen), has been sold abroad under several names, including "Abstral[®]." In Europe, ProStrakan (Galashiels, Scotland, UK; CEO: Thomas Stratford), a subsidiary of Kyowa Hakko Kirin, sells this drug under the name of "Abstral[®]."

In the field of treatment for cancer pain, Kyowa Hakko Kirin and Hisamitsu Pharmaceutical have been jointly selling the transdermal, long-acting cancer pain relief patch Fentos® Tape since June 2010. We would like to continue to contribute to the improvement of QOL of patients suffering from cancer pain through comprehensive information release to healthcare professionals and information collection from them.

Product summary for Abstral®

Brand name	Abstral [®] sublingual tablet 100μg, 200μg and 400μg
Nonproprietary name	fentanyl citrate
Indications	For the management of breakthrough pain in cancer patients who are already
	receiving and who are tolerant to around-the-clock opioid therapy for their
	underlying persistent cancer pain.
Approval date	September 20, 2013
Date of NHI Drug	November 19, 2013
Price Listing	
Package	100μg:40 tablets, 200μg:40 tablets, 400μg:40 tablets
Drug price	573.60 yen/100μg tablet, 800.40 yen/200μg tablet,1,116.80 yen/400μg tablet