Announcement regarding the Marketing Approval of Abstral® sublingual tablets for Cancer Pain Treatment

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu city, Saga prefecture, Japan; President and CEO: Hirotaka Nakatomi, hereinafter referred to as "Hisamitsu") announced the receipt of a report that Kyowa Hakko Kirin Co., Ltd. (Head Office: Chiyoda-ku, Tokyo , Japan; President and CEO: Nobuo Hanai , hereinafter referred to as "Kyowa Hakko Kirin") has been approved for manufacturing and marketing for the cancer pain drug Abstral® sublingual tablet $100~\mu g$, $200~\mu g$, and $400~\mu g$ (Development code: KW-2246, Active pharmaceutical ingredient: fentanyl citrate, hereinafter referred to as "the product") in Japan as of today.

The product was licensed by Kyowa Hakko Kirin from Orexo AB.(Head Office: Uppsala, Sweden, President and CEO: Nikolaj Sørensen). The drug is indicated for the treatment of the sudden pain (breakthrough pain) that occurs during sustained management of cancer pain, and the main effect is the rapid absorption of fentanyl and an analgesic effect enabled by sublingual administration. Kyowa Hakko Kirin submitted the application for market approval in November 2012 after confirmation of product efficacy and safety in clinical studies conducted in Japan.

Hisamitsu obtained the rights to joint distribution in Japan in February 2010, and the distribution of the product and the provision of information after market will be conducted separately by the two companies (2 channels for 1 brand). In addition, Hisamitsu and Kyowa Hakko Kirin are conducting the joint distribution of the transdermal, long-acting cancer pain relief patch Fentos® Tape, which was launched in June 2010.

Hisamitsu will contribute to the improvement in the quality of life of patients suffering from cancer pain by comprehensive provision and collection of information through the marketing of the transdermal, long-acting cancer pain relief patch Fentos® Tape, the transdermal, long-acting cancer pain relief patch Fentanyl 3-day tape HMT, which was launched in July 2012, and the new addition of Abstral® for the treatment of breakthrough pain.