

**Notice of Filing of New Drug Application for Approval to
Manufacture and Sell Cancer Pain Drug KW-2246**

Hisamitsu Pharmaceutical Co., Inc., (Head Office: Tosu-City, Saga Prefecture, Japan; Representative Director, President and CEO: Hirotaka Nakatomi; hereinafter referred to as “Hisamitsu Pharmaceutical”) today announced that on November 13, 2012, Kyowa Hakko Kirin Co., Ltd., (Head Office: Chiyoda-ku, Tokyo, Japan; Representative Director, President and CEO: Nobuo Hanai; hereinafter referred to as “Kyowa Hakko Kirin”) filed a new drug application for approval to manufacture and sell KW-2246 (fentanyl citrate sublingual tablets), which is currently under development as a cancer pain drug.

KW-2246 is a drug for the treatment of acute pain (breakthrough pain) that comes when managing to control persistent cancer pain; the drug is capable of rapidly producing analgesic effects with the rapid absorption of fentanyl after sublingual administration. Kyowa Hakko Kirin has in-licensed KW-2246 from Orexo AB in Uppsala, Sweden (President and CEO: Anders Lundström). Hisamitsu Pharmaceutical acquired the joint distribution rights for KW-2246 in Japan from Kyowa Hakko Kirin in February 2010.

Kyowa Hakko Kirin filed a new drug application to manufacture and sell KW-2246 in February 2010 but subsequently withdrew its application, considering that further accumulation of clinical data would be necessary in addition to the existing materials submitted for the application. Since then, Kyowa Hakko Kirin has been conducting additional clinical studies of the drug. As the effectiveness and safety of this drug have been further validated through these additional clinical studies, Kyowa Hakko Kirin has filed a new drug application to manufacture and sell KW-2246 this time.

By adding KW-2246 for the treatment of breakthrough pain to its existing line of transdermal patches for the treatment of persistent cancer pain, i.e. Fentos[®] Tape for once daily application (launched in June 2010) and Fentanyl 3-Day Tape [HMT], which is suitable for application once every three days (launched in July 2012), Hisamitsu Pharmaceutical will provide comprehensive information on cancer pain treatment, thereby contributing to the improvement of the quality of life of patients experiencing cancer pain.