

Conduct of Additional Clinical Study of KW-2246, a Cancer Pain Drug

Hisamitsu Pharmaceutical Co., Inc., (Head Office: Tosu, Saga; President: Hirotaka Nakatomi; hereinafter referred to as “Hisamitsu Pharmaceutical”) announced today that it was informed by Kyowa Hakko Kirin Co., Ltd., (hereinafter referred to as “Kyowa Hakko Kirin”) that Kyowa Hakko Kirin had decided to conduct an additional clinical study of KW-2246, a cancer pain drug. Hisamitsu Pharmaceutical was also informed that Kyowa Hakko Kirin decided to temporarily withdraw its application for approval because it would take time to conduct the additional clinical study.

KW-2246 is for a treatment of acute pain (breakthrough pain) during the management of sustained cancer pain that Kyowa Hakko Kirin has in-licensed from Orexo AB (Head Office: Uppsala, Sweden; CEO: Torbjörn Bjerke) with the expectation that the drug is rapidly absorbed and exerts an analgesic effect following sublingual administration. In February 2010, Hisamitsu Pharmaceutical obtained joint distribution rights in Japan from Kyowa Hakko Kirin, which submitted its application for marketing approval the same month.

Since June 24, 2010, Hisamitsu Pharmaceutical has been distributing Fentos® Tape, a transdermal patch for the treatment of sustained cancer pain. By adding KW-2246, a drug for the treatment of breakthrough pain, to this and providing comprehensive information, Hisamitsu Pharmaceutical will contribute to improving the quality of life for patients who experience cancer pain.