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Orexo re-submits NDA for cancer pain killer in Japan

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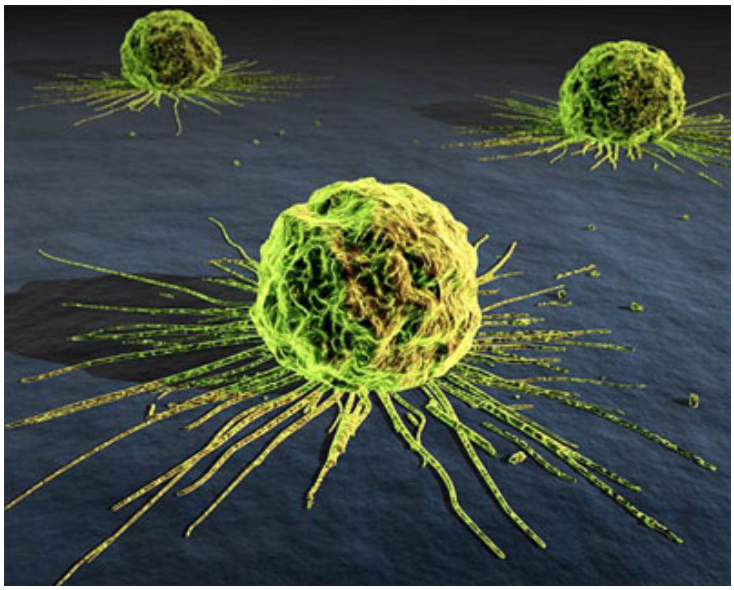

Singapore: Swedish specialty pharmaceutical company, Orexo, revealed that that its partner Kyowa Hakko Kirin submitted a new drug application (NDA) in Japan for KW-2246 (Abstral), a fentanyl sublingual tablet developed for the treatment of breakthrough cancer pain.

KW-2246 (Abstral) is a rapidly-disintegrating, sublingual (under the tongue) formulation of fentanyl. The product has previously been approved in the US, EU and Canada for the management of episodes of breakthrough pain experienced by cancer patients who already are receiving opioid analgesics for chronic pain.

On February 24, 2010, a NDA application covering KW-2246 (Abstral) was submitted for approval in Japan. The application was subsequently withdrawn and additional clinical trials were performed. Following confirmation of the product efficacy and safety in these trials, the current application has now been submitted.

On June 1, 2012, Orexo renegotiated the Abstral agreement with ProStrakan, a subsidiary of Kyowa Hakko Kirin, and acquired all rights to Abstral in the US. ProStrakan acquired the corresponding rights in the EU and rest of the world excluding Japan, which already were controlled by their owner.

As announced on February 2, 2010, KW-2246 will be jointly marketed and sold in Japan by Kyowa Hakko Kirin and Hisamitsu Pharmaceutical. The two companies have since June 2010 jointly been selling another cancer pain product, FentosTape (fentanyl citrate transdermal product).