



**Press release - Uppsala, Sweden – November 13, 2012**

## **Orexo announces submission of a New Drug Application for KW-2246 (Abstral®) in Japan**

**Swedish specialty pharmaceutical company Orexo today communicated that its partner Kyowa Hakko Kirin Co., Ltd has 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 The application was subsequently withdrawn and additional clinical trials were performed.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 Co. Ltd, 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 Co., Inc. The two companies have since June 2010 jointly been selling another cancer pain product, Fentos® Tape (fentanyl citrate transdermal product).

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### **About Orexo**

Orexo AB is an emerging specialty pharma company developing improved treatments using proprietary drug delivery technology. Orexo's expertise is within the area of reformulation technologies and especially sublingual formulations. The company has a portfolio of revenue-generating US and EU approved products currently marketed under licence and a pipeline of several reformulations of approved compounds for areas of unmet medical need. Orexo also has collaboration projects with several international pharma companies. Orexo AB with its headquarters in Sweden has 100 employees and is listed on NASDAQ-OMX. The largest shareholders are Novo A/S and HealthCap.

### **About KW-2246 (Abstral®)**

KW-2246 (Abstral) is a rapidly-disintegrating, sublingual (under the tongue) formulation of fentanyl, a well-established opioid used for the management of episodes of breakthrough pain experienced by cancer patients who are already receiving opioid analgesics for chronic pain. Abstral is approved in the US, EU and Canadian markets.

### **About Kyowa Hakko Kirin**

Kyowa Hakko Kirin Co., Ltd. is engaged in the manufacturing and marketing of medical products and pharmaceuticals. As the parent company of the Kyowa Hakko Kirin Group, it manages the business activities in the Bio-Chemicals segment with the Pharmaceuticals segment as its core business. More information can be found at <http://www.kyowa-kirin.com>.

For more information about Orexo please visit [www.orexo.com](http://www.orexo.com)

*Orexo is required under the Financial Instruments Trading Act to make the information in this press release public. The information was submitted for publication at 08:15 am CET on November 13, 2012.*