# orexo

### Press release - February 25, 2010

## Orexo announces Kyowa Hakko Kirin's submission of KW-2246 (Abstral) for approval in Japan

**Uppsala, February 25, 2010** — Orexo AB (STO: ORX) today announces that its partner Kyowa Hakko Kirin Co., Ltd. has submitted the New Drug Application (NDA) in Japan for the cancer pain drug KW-2246 (Abstral).

Kyowa Hakko Kirin has confirmed KW-2246's safety and efficacy in clinical trials conducted in Japan.

The drug will be marketed by Kyowa Hakko Kirin and Hisamitsu Pharmaceutical Co., Inc. Kyowa Hakko Kirin and Hisamitsu will also market HFT-290 (Fentanyl transdermal patch) under development by Hisamitsu.

Commenting on the announcement, Torbjörn Bjerke, Orexo's President and CEO, said: "The submission of KW-2246 in Japan is an important step in the international development of Orexo's sublingual fentanyl product, in Europe launched under the brand Abstral<sup>TM</sup>. The success of Abstral is confirmed by its strong sales growth in Europe.

This submission further strengthens that Orexos sublingual fentanyl product has the potential to be an important product for the treatment of severe pain episodes in cancer patients globally. The submission is a result of the continued strong commitment we see from our partner Kyowa Hakko Kirin in the Japanese market."

#### For further information, contact:

Torbjörn Bjerke, President and CEO Tel: +46 (0)708-66 19 90 E-mail: torbjorn.bjerke@orexo.com

Claes Wenthzel, Executive Vice President and CFO Tel: +46 (0)708-620 122 E-mail: claes.wenthzel@orexo.com

#### About Abstral<sup>TM</sup>(KW-2246)

Abstral<sup>TM</sup> is a fast-disintegrating tablet for sublingual administration of fentanyl, intended for the management of breakthrough cancer pain in patients who are already receiving opioid analgesics. It is based on Orexo's unique and patented sublingual tablet technology in which a rapidly disintegrating tablet is placed under the tongue and the active substance is absorbed by the mucous membrane. Currently Abstral<sup>TM</sup> is sold in Sweden, UK, Germany, Spain, Greece and France. An NDA for Abstral<sup>TM</sup> has been filed in the US by the partner ProStrakan. In Japan a registration application has been submitted by the partner Kyowa Hakko Kirin.

#### **About Orexo**

Orexo is a pharmaceutical company focusing on developing treatments for pain and inflammation. The company has four products on the market as well as a broad project portfolio in late stages of development. Sales and product development are mainly carried out through worldwide partnership agreements with larger pharmaceutical companies. Orexo has 108 employees, and has its head office located in Uppsala, Sweden. More information can be found at www.orexo.com.

#### 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 and Chemicals segments with the Pharmaceuticals segment as its core business. More information can be found at http://www.kyowa-kirin.co.jp/english/index.html.

Note:

*This is information that Orexo AB (publ) is required to disclose pursuant to the Swedish Financial Instruments Trading Act and/or the Swedish Securities Markets Act. The information was provided for public release on 25<sup>th</sup> February, 2010 at 08:00 CET.*