Press release, July 24, 2009

Orexo announces positive Phase III results for KW-2246 in Japan

Orexo's partner in Japan, Kyowa Hakko Kirin, has obtained positive phase III results in Japan for KW-2246, which is approved for the treatment of breakthrough pain in cancer patients and marketed under the brand Abstral™ in Europe. Kyowa Hakko Kirin will now proceed with preparations for a new-drug application for KW-2246 in Japan for use in continuous pain management of acute cancer pain (breakthrough pain).

Uppsala, Sweden, 24 July, 2009 – Orexo (STO: ORX) announces that Kyowa Hakko Kirin, Orexo's partner in Japan, today confirms that it has obtained positive clinical phase III results for KW-2246 in Japan. The clinical study results revealed a statistically significant difference between KW-2246 and the placebo, and clinical effectiveness was confirmed. In addition, with regard to safety, no unacceptable side effects were found during the clinical study period.

Kyowa Hakko Kirin will now proceed with the preparations for a new-drug application for KW-2246 in Japan. According to the market research institute Datamonitor, the Japanese market for opioids is one of the largest markets in the world (Datamonitor 2008, Commercial and Pipeline Insight: Opioids).

Torbjörn Bjerke, President and CEO of Orexo, comments: "The positive phase III results in Japan are an important milestone for our successful collaboration with Kyowa Hakko Kirin. This marks another important step in the international development of Abstral™ and strengthening Orexo in the process of becoming a profitable pharmaceutical company".

Trial design
The clinical study was conducted using a crossover design involving a double-blind placebo-controlled trial, targeting patients to whom an opioid analgesic was administered at fixed intervals for intermediate to severe cancer pain and who use a morphine preparation for breakthrough pain, and a non-blind controlled trial with a morphine preparation.

VISIT Virdings allé 32 A
WEB www.orexo.com
E-MAIL info@orexo.com
POST Orexo AB
BOX 303
SE-751 05 Uppsala
Sweden
PHONE +46 (0)18 780 88 00
FAX +46 (0)18 780 88 88
CORP. REG. NO. 556500-0600

For further information, contact:

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

Johan Andersson, Investor Relations Manager
Tel: +46 (0)702-100 451
E-mail: johan.andersson@orexo.com

About Abstral

Abstral is a fast-dissolving tablet for sub-lingual 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 dissolving tablet is placed under the tongue and the active substance is absorbed by the mucous membrane. Currently Abstral is sold in Sweden, UK and Germany and is ready for launch in France. In Sweden, Abstral is sold through Orexo's and ProStrakan's joint venture, ProStrakan AB. The product is being prepared for registration in Japan and in the US the clinical phase III is finalized.

License agreements have been signed with Kyowa Hakko Kirin for Japan and with ProStrakan for EU and the US. Distribution agreements regarding Abstral for Russia and the CIS, Bulgaria and Rumania have been signed with Gedeon Richter. A distribution agreement has been signed with Hospira for the Southeast Asian market. For the Chinese market, Orexo has signed a distribution agreement with NovaMed, and for the Israeli market Orexo has signed a distribution agreement with Neopharm.

About Orexo

Orexo is a pharmaceutical company focusing on developing treatments for pain and inflammation. The company has four commercialized products 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 128 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:
Orexo AB (publ) is required to disclose the information provided herein pursuant to the Swedish Securities Markets Act. The information was provided for public release on July 24, 2009 at 08:00 CET.