Press release, 6th October 2009

Orexo confirms FDA acceptance of Abstral filing

Uppsala, Sweden, 6th October, 2009 - Orexo AB (STO: ORX) today confirms that its partner, ProStrakan Group plc (LSE: PSK), has announced that the New Drug Application (NDA) filing for Abstral has been accepted for review by the US Food and Drug Administration (FDA).

Abstral is a new, rapidly disintegrating, sublingual formulation of fentanyl, a long-established opioid used for the management of episodes of breakthrough pain experienced by cancer patients who are already receiving opioid analgesics for their chronic pain.

Subject to successful completion of the US approval process, ProStrakan plans to launch Abstral in the US in the second half of 2010.

Commenting on today's announcement, Torbjörn Bjerke, Orexo's President and CEO, said: "FDA's acceptance of the Abstral NDA filing is an important step towards bringing this product to the thousands of patients in the US that we believe will benefit from its effective and convenient formulation. The US is the world's largest market for breakthrough cancer pain with the number of attacks amounting to approximately 376 million per year(1). We are very excited at the prospect of our partner ProStrakan launching Abstral in the second half of 2010".

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1) Source: Datamonitor 2006, Pipeline Insight: Breakthrough Pain

About Abstral

Abstral is a fast-dissolving 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 dissolving tablet is placed under the tongue and the active substance is absorbed by the mucous membrane. Currently Abstral is sold in Sweden, UK, Germany and France. The product is also being prepared for registration in Japan.

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

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 128 employees, and has its head office located in Uppsala, Sweden. More information can be found at www.orexo.com.

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 6th October, 2009 at 08:20 CET.

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