



Press release, February 22, 2011

Abstral® approved in Canada

Uppsala, Sweden– February 22, 2010 – Orexo AB (STO: ORX) today announces that ProStrakan's partner, Paladin Labs Inc. has been informed by Health Canada, the Canadian Government Department with responsibility for public health, that it has approved Abstral®.

Abstral is a rapidly-disintegrating, sublingual (under the tongue) formulation of fentanyl. The product is approved for the treatment of breakthrough pain in patients receiving opioid analgesics for underlying chronic cancer pain.

Orexo has out-licensed the rights for Abstral in Europe and North America to ProStrakan. The rights to the Canadian markets were sub-licensed by ProStrakan to Paladin in 2008. Orexo will receive royalty on sales in Canada and payment on achievement of certain sales targets.

Abstral was in January 2011 approved by the US Food and Drug Administration, where ProStrakan plans to launch this product in Q1 2011.

Anders Lundström, Orexo's President and CEO, said: "We are very pleased to be able to announce this approval. The Canadian pharmaceutical market is significant – one of the top 10 markets in the world, and one of the fastest growing. We are confident that Paladin will be an excellent partner for ProStrakan and Orexo in enabling Canadian patients suffering from breakthrough cancer pain to get better relief with Abstral. This is another important step for Orexo in providing the right solutions to pain for clinicians and their patients."



For further information please contact:

Anders Lundström, President & CEO

Tel: +46 (0)70-667 22 66

Email: anders.lundstrom@orexo.com

Robin Wright, EVP and CFO

Tel: +44 7720 300025

Email: robin.wright@orexo.com

About Abstral®

Abstral is a fast-acting and rapidly disintegrating sublingual tablet formulation of fentanyl citrate designed for oral transmucosal delivery. The product offers patients and clinicians a simple, patient friendly and predictable way of delivering fentanyl transmucosally while retaining the individualized dose titration aspects required for optimal treatment of breakthrough pain.

Abstral was approved for marketing in the US in January 2011. ProStrakan will launch Abstral in the US during Q1 2011. Abstral will be the only fast-acting sublingual tablet for breakthrough cancer pain in the US market. The overall annual market value in the US for fast-acting fentanyl products is \$550m (source: Wolters Kluwer, August 2010. MAT). ProStrakan started sales of Abstral in Europe in 2009. During 2010, sales amounted to GBP 17 million. By June 2010, the product had an average share of 24% of the fast-acting fentanyl market across the five largest European markets (source: IMS, June 2010).

About Orexo

Orexo is a pharmaceutical company focusing on developing treatments for pain and inflammation. Orexo is developing proprietary products based on its proven reformulation technologies, targeted at the Specialty Pharmaceutical market. Orexo intends to commercialize some of these products itself in one or more major markets. Its development activity builds on Orexo's core competences in R&D, which have previously resulted in several successful products, currently out-licensed through worldwide partnership agreements to larger pharmaceutical companies. Today, Orexo has four products on the market of which Abstral is a leading product for the treatment of breakthrough pain in cancer patients. Orexo also has three significant partnerships with major pharmaceutical companies for research and development programs: discovery stage collaborations with Ortho-McNeil Janssen and Janssen Pharmaceutica in respiratory inflammation and with Boehringer Ingelheim for inflammation and pain, both within the arachidonic acid cascade and a clinical stage development agreement



with Novartis for the treatment of gastrointestinal disorders. Orexo's head office is 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 Securities Markets Act. The information was provided for public release on February 22, 2011 at 14:30 a.m. CET.