Press release, January 10, 2011

FDA Approval for Abstral® (Fentanyl) Sublingual Tablets - US launch planned for Q1 2011

Uppsala, January 10, 2011 - Orexo AB (STO: ORX) announces today that its partner ProStrakan Group plc (LSE: PSK) has received approval from the US Food and Drug Administration (FDA) for Abstral®. Abstral® is licensed for the treatment of breakthrough pain in cancer patients, 18 years of age and older, who are already receiving, and are tolerant to, opioid analgesics for their underlying persistent cancer pain. "This is an important step for patients with cancer pain to have options for the treatment of their breakthrough pain," said John Jenkins, M.D., director of FDA's Office of New Drugs in the Center for Drug Evaluation and Research.

ProStrakan expects to launch Abstral® in the US during Q1 2011. Launch preparations are at an advanced stage and sales teams have already completed a significant level of training. Abstral® will be the only fast-acting sublingual tablet for breakthrough cancer pain on the US market, where the overall annual market value for fast-acting fentanyl products is $550m. *(Source: Wolter Kluwers, August 2010. MAT).*

Abstral® is the first product to be approved in the US with the FDA mandated class Risk Evaluation and Mitigation Strategy (REMS) for transmucosal immediate release fentanyl products. The Abstral® REMS allows appropriate prescriptions to be filled at retail pharmacies as well as providing access to Abstral® within hospitals. "This approval is also a significant step toward reducing the burden on the health care system of implementing REMS programs," added Dr. Jenkins. "When fully implemented, FDA expects that prescribers, pharmacies, and distributors of all immediate release transmucosal fentanyl products will be able to use standardized materials and a single shared system to implement the REMS."

Abstral is a fast-acting and rapidly disintegrating sublingual tablet formulation of fentanyl citrate designed for oral transmucosal delivery. The product offers an alternative therapeutic choice to patients and clinicians with a simple, patient

friendly and predictable way of delivering fentanyl transmucosally while retaining the individualised dose titration aspects required for optimal treatment of breakthrough pain.

Breakthrough pain is an acute and often severe flare of pain, experienced by patients suffering from cancer, which occurs even though a person may be taking opioid pain relief medicine regularly for their persistent pain. It is known as breakthrough pain because it "breaks through" a regular pain medicine schedule. It may be caused by the cancer itself or it may be related to cancer treatment.

Abstral® has been a significant driver of growth for ProStrakan in Europe. The product is now marketed by ProStrakan across the principal European markets – UK, Germany, France, Spain, Italy and Sweden. By June 2010 the product had gained an average share of 24% of the fast-acting fentanyl market across these countries (Source: IMS, June 2010), and recorded Europe-wide sales of £14.1m in the first 10 months of 2010.

Torbjörn Bjerke, President and CEO of Orexo

"This US approval of Abstral® is very good news not just for Orexo, but also for the population of cancer patients experiencing very severe pain. This will enable us, through our partner ProStrakan, to provide these patients with very fast, and effective relief from pain in a responsible and managed way. Abstral® is already making a big difference to patients throughout Europe and will soon be launched in other countries as well. Orexo is receiving between 25-30 percent royalties on net sales of Abstral® in Europe and will receive between 23-28 percent royalties on net sales in the US. This is another important step towards making Orexo a specialty pharmaceutical company."

Peter Allen, Chairman & Acting Chief Executive of ProStrakan, said:

"FDA approval of Abstral® is another significant step forward for ProStrakan, enabling us to launch our second major oncology support product in the US, the world's largest pharmaceutical market. Abstral® is already being prescribed for patients across Europe who suffer the debilitating effects of breakthrough cancer pain and we believe that the benefits of Abstral's rapid pain relief will be recognised by both clinicians and patients in the US."

To the editors

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About Abstral®

- Abstral® is a fast-acting and rapidly disintegrating tablet for sublingual (under the tongue) administration of fentanyl intended for the management of breakthrough pain in cancer patients who are already receiving opioid analgesics for their underlying persistent cancer pain.
- Abstral® was launched in the principal European markets during the course of 2009 and generated sales of £14.1m in the first ten months of 2010 in Europe.
- In the top four European markets (Source: IMS data June 2010). Abstral® achieved in June 2010 a 24% market share by tablet volume of short-acting fentanyl products. (Source: IMS data June 2010).

About Breakthrough Cancer Pain

Breakthrough pain ("BTP") is an acute and often severe flare of pain, experienced by patients treated with round the clock opioid analgesics for their underlying chronic cancer pain. It is known as breakthrough pain because it "breaks through" a regular pain medicine schedule. For some patients, breakthrough pain occurs during certain everyday activities, such as walking or dressing. For others, it occurs unexpectedly without any apparent cause.

In a recent survey of patients with cancer BTP:

- 89% stated that BTP negatively affected their quality of life
- 73% stated that BTP wakes them from a deep sleep at least once a month
- 76% stated that BTP affects their ability to perform everyday household chores
- 75% stated that BTP is one of the most challenging effects of having cancer
- 35% stated that BTP affects their relationships with their family members

- 82% stated that BTP negatively affects their emotional health

The American Pain Foundation. Breakthrough Cancer Pain Survey Fact Sheet.

Available at: ***http://www.painfoundation.org/learn/programs/spotlight-on-cancer-pain/breakthrough-pain/btcp-survey-fact-sheet.pdf***

About the Abstral Risk Evaluation and Mitigation Strategy (REMS)
The Abstral® REMS program will allow the dispensing of Abstral in retail pharmacies across the US, once they are enrolled in the program. ProStrakan has partnered with Relay Health to develop and deliver an innovative REMS program for Abstral® that is designed to integrate with the pharmacy management system to automatically verify that all REMS requirements have been met prior to the pharmacist dispensing Abstral®. The Abstral® REMS program has been designed to minimise burden on prescribers and pharmacies and allow appropriate patient's access to Abstral®.
The goals of the Abstral® REMS are to mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors by:

- Prescribing and dispensing Abstral® only to appropriate patients, which includes use only in opioid-tolerant patients.
- Preventing inappropriate conversion between fentanyl products.
- Preventing accidental exposure to children and others for whom it was not prescribed.
- Educating prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose.

The FDA has requested that all immediate-release fentanyl products are brought within a single REMS model and then within a single REMS system within 2011. It is anticipated that the Abstral® REMS will be very similar to the class-wide REMS for all immediate-release fentanyl products.

As part of the approval, ProStrakan has agreed to conduct a post-approval clinical study of Abstral® in children.

Common adverse reactions to Abstral® include nausea, constipation, drowsiness and headache. Serious adverse reactions, including deaths, have occurred with other immediate-release fentanyl products. Deaths have occurred because of improper selection of patients and/or incorrect dosing.

A full copy of the FDA press release related to the approval of Abstral® can be found at:
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm239490.htm.

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 commercialise 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 in most of Europe. 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**.

About ProStrakan

ProStrakan Group plc is a rapidly growing specialty pharmaceutical company engaged in the development and commercialisation of prescription medicines for the treatment of unmet therapeutic needs in major markets.
ProStrakan's head office is located in Galashiels in Scotland. The company's development capabilities are centered in Galashiels and Bedminster, New Jersey, USA. Sales and marketing of ProStrakan's portfolio of products are handled by commercial subsidiaries in the UK, US, France, Germany, Spain, Italy and other EU countries.

You can learn more about ProStrakan at **www.prostrakan.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 January 10, 2011 at 08:00 a.m. CET.