

**Press release, April 4, 2011**

## **Abstral® launched and now available in the United States**

**Uppsala, April 4, 2011** - Orexo AB (STO: ORX) announces today that its partner ProStrakan Group plc (LSE: PSK) has launched Abstral in the United States.

Abstral, which is the only fast-acting sublingual tablet for the treatment of breakthrough cancer pain, is now available to patients in the US. In 2010 the market value for fast-acting fentanyl products was \$530m. (*Source: Wolter Kluwers*).

Abstral was approved by the US Food and Drug Administration (FDA) in January 2011, and 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 the product within hospitals.

Abstral is already marketed by ProStrakan across the principal European markets. In 2010 the product achieved an average market share of 24% of the fast-acting fentanyl market in these countries (Source: IMS, 2010), and recorded Europe-wide sales of £17.3m.

### ***Anders Lundström, President and CEO of Orexo***

“We are pleased that Abstral has been launched on the world’s largest pharmaceutical market and that also the cancer patients in the United States can be treated with Abstral for fast and effective relief from breakthrough pain.”



## **To the editors**

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### **About the Abstral Risk Evaluation and Mitigation Strategy (REMS)**

The Abstral REMS program allows the dispensing of Abstral in retail pharmacies across the US. ProStrakan has partnered with Relay Health to implement 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 class-wide REMS for all immediate-release fentanyl products will be very similar to the Abstral REMS.



## **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 and now also in the United States. 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](http://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](http://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 April 4, 2011 at 2:15p.m. CEST.*