

**Press release 2<sup>nd</sup> March, 2009**

## **Orexo's Abstral™ receives two further large EU market approvals in France and Spain**

Orexo (NASDAQ-OMX:ORX), announces that Abstral™ has received Marketing Authorisation from the French and Spanish regulatory authorities for the treatment of breakthrough cancer pain.

Abstral™ is expected to be launched during the second half of 2009 in France and Spain, following pricing and reimbursement negotiations with the relevant authorities, by ProStrakan (LSE:PSK), Orexo's exclusive licensing partner for Abstral™ in Europe and North America. The two new approvals mean that Abstral™ has been approved in five European markets including Sweden, the UK and Germany since March of 2008, with further approvals anticipated in 2009. The approvals in France and Spain trigger milestone payments of EUR 1.3 million to Orexo.

Commenting on the news, Torbjörn Bjerke, President and CEO of Orexo, said "Abstral™ is a very important product for helping cancer patients manage their pain and with this approval patients across the majority of the European market can now benefit from the product. The royalty stream that this product will generate will bring us closer to our goal of becoming a sustainable, profitable pharmaceutical company. ProStrakan is doing an excellent job of rolling out Abstral™ to the major European markets, and together we are anticipating to be in a position to file for USA approval for the product in 2009. We look forward to continuing our successful partnership with ProStrakan in Europe and North America in the near future."

Abstral™ is a sublingual (under the tongue) tablet for the fast administration of fentanyl, an opioid commonly used to treat breakthrough cancer pain in patients who are already receiving opioid analgesics. Abstral™'s formulation is based on Orexo's unique sublingual tablet technology in which a rapidly dissolving tablet is placed under the tongue and the active substance is absorbed by the mucous membrane, resulting in very rapid pain relief for patients suffering from breakthrough pain.

Abstral™ received a positive recommendation for approval in Europe by the EMEA's Committee for Medicinal Products for Human Use in June 2008. It is currently launched in reference country Sweden, the UK and Germany.

ProStrakan is Orexo's exclusive licensing and distribution partner for Abstral™ in Europe and North America. Orexo also recently signed a licensing and distribution agreement for

Abstral™ with NovaMed for China and with Neopharm for Israel. Orexo already has other partnership agreements for Abstral™ in Eastern Europe and the CIS with Gedeon Richter, in Japan with Kyowa Hakko Kirin and for the other territories in Southeast Asia with Hospira.

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**Notes to Editors**

**About Orexo**

Orexo is a pharmaceutical company focusing on developing treatments for pain and inflammation. The company has three products on the market as well as a competitive product 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.

**Product portfolio**

**Commercialised products with distribution- and marketing agreements**

Product	Indication	Status
Abstral™/Rapinyl	Acute pain	Marketed in EU, Phase III in US and Japan Partnered with: ProStrakan, Gedeon Richter, Hospira, Kyowa Hakko Kirin, Neopharm and NovaMed
Diabact® UBT	Diagnosis - <i>Helicobacter pylori</i>	Marketed in EU and other territories*
Heliprobe™ System	Diagnosis - <i>Helicobacter pylori</i>	Marketed in EU and other territories*

*\*Marketed through Kibion AB, subsidiary of Orexo*

**Outlicensed development projects - deals with future milestones and royalties**

Product	Indication	Development phase	Partner(s)
Sublinox™	Insomnia	Registration	Meda
OX-NLA	Rhinitis	Phase III-ready	Meda
OX-MPI	Pain, inflammation	Pre-clinical development	Boehringer Ingelheim

**Prioritized projects for which licensing discussions have begun**

Product	Indication	Development phase
OX17	GERD	Phase II/III – in development agreement
OX914	COPD/Asthma	Phase II
Arachidonic Acid Franchise (OX2477/OX-CLI)	Asthma/COPD	Pre-clinical
OX641	Migraine	Pre-clinical
OX-PKX	Various projects with the PharmaKodex platform	
OX19	Incontinence	Phase I PK Study

#### Projects with potential for further development

OX-LSAID	Asthma	Phase II
OX219	Opioid addiction	Early clinical phase
OX30	Abuse-Proof Pain medication	Formulation

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 situated in Galashiels in Scotland. The company's development capabilities are centred on 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 and other EU countries.

More information can be found at [www.prostrakan.com](http://www.prostrakan.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 approved for marketing in France and Spain.

The product Abstral™ is also known as Rapinyl in the US and some other territories.

#### Breakthrough cancer pain

It is estimated that there are in excess of five million people with cancer in Europe <sup>(1)</sup>, that 30% of these suffer pain as a result<sup>(2)</sup> and that 65% of these have breakthrough cancer pain<sup>(3)</sup>.

Breakthrough cancer pain is a brief and often severe flare of pain experienced by patients suffering from cancer that occurs even though a person may be taking pain relief medicine regularly for their persistent pain. It is known as breakthrough pain because it is pain that "breaks through" a regular pain medicine schedule. It may be caused

by the cancer itself or it may be related to cancer treatment. For some people, breakthrough pain occurs during certain everyday activities, such as walking or dressing. For others, it occurs unexpectedly without any apparent cause.

*Sources:*

*(1) Cancer Prevalence in European Registry Areas. Micheli et al, Annals of Oncology 13: 840-865, 2002*

*(2) Management of Cancer Pain. Levy M., & Samuel, T Semin Oncol 32: 179-193, 2005*

*(3) Breakthrough Cancer Pain Characteristics and Syndromes in Patients with Cancer Pain. An International Survey. Caraceni et al, Palliative Medicine 2004; 18: 177 et seq*

*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 March 2, 2009 at 08:00 CET.*