

Press release June 26, 2008

Orexo report Abstral (Rapinyl) approval in Europe

Uppsala, Sweden, 26 June, 2008 – Orexo AB (OMX: ORX), the Swedish pharmaceutical company, announces that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending approval of Rapinyl, for breakthrough cancer pain. ProStrakan Group plc, the international speciality pharmaceutical is Orexo's exclusive partner for sales and marketing of Abstral/Rapinyl in Europe. Abstral/Rapinyl will be launched in Sweden in Q3 2008 and, as a result of today's announcement, across Europe from the end of 2008 under the brand name Abstral.

Abstral is a fast disintegrating tablet for sublingual administration of fentanyl intended for the management of breakthrough cancer pain in patients who are already receiving opioid analgesics. Abstral is based on Orexo's unique proprietary technology for sublingual administration.

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

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. For some people, breakthrough pain occurs during certain everyday activities, such as walking or dressing. For others, it occurs unexpectedly without any apparent cause.

Abstral was referred to the CHMP for review in September 2007 and has now gained a positive opinion recommending approval of the product. This will allow ProStrakan to obtain national licences throughout the EU, with launches following their receipt.

In March 2008, Abstral received a Marketing Authorisation for Sweden, which was the Reference Member State (RMS) for the product during the decentralised procedure.

Commenting on Abstral's European approval, Dr Torbjörn Bjerke, President and Chief Executive of Orexo, said:

"The approval is a fantastic achievement for Orexo and our ability to become a profitable pharmaceutical company. I believe that Abstral will play a major role in the treatment of cancer patients suffering from breakthrough pain."

"We are very excited to launch Abstral in Sweden as the first country in our joint venture with ProStrakan, which operates in the Nordic countries. I look forward to continue our excellent partnership with ProStrakan"

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

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TO THE EDITORS

About Orexo

Orexo is a pharmaceutical company, focusing on development of new, patented drugs by combining well-documented substances with innovative technologies, and the development of new treatments for respiratory and inflammatory diseases.

Orexo has a broad and competitive late-stage product portfolio, including two marketed products, five products in clinical phase and two undergoing registration.

To date, Orexo have out-licensed the market rights for Rapinyl for the US, the EU and Japan markets, the world-wide market rights for Sublinox (OX22) and OX-NLA, and a out-license and research collaboration with Boehringer Ingelheim regarding the development of a new class of drugs to treat pain and inflammation. Also, Orexo has established a Nordic sales force by entering into a joint venture with ProStrakan.

Orexo has head office in Uppsala and is listed on the OMX Nordic Exchange Stockholm, Small Cap (ticker: ORX).

www.orexo.com

About ProStrakan

ProStrakan Group plc is a rapidly growing international 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 and development facilities are situated in Galashiels in Scotland. EU-wide sales and marketing of ProStrakan's portfolio of products are handled by commercial subsidiaries in the UK, France, Germany, Spain and other EU countries. ProStrakan has recently commenced the expansion its operations into the US.

www.prostrakan.com

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