

Press release 23 September, 2008

UK Marketing Approval Issued for Abstral

Orexo AB (OMX: ORX) confirms the announcement made by ProStrakan Group plc (LSE: PSK), Orexo's partner for Abstral® in Europe and North America, that the UK Medicines and Healthcare products Regulatory Agency (MHRA) has issued a Marketing Authorisation for Abstral (for breakthrough cancer pain). As a result of the approval, Orexo will receive a milestone payment of USD 1 million.

This earlier than expected authorisation will enable ProStrakan to complete UK pricing negotiations and launch planning by the end of 2008, enabling UK sales of Abstral to make a full contribution in 2009.

Abstral (formerly branded as Rapinyl) is a fast-dissolving tablet for sub-lingual (under the tongue) administration of fentanyl intended for the management of breakthrough cancer pain in patients who are already receiving opioid analgesics. Orexo AB has a licence agreement with ProStrakan regarding the exclusive rights to this product in Europe and North America.

The Committee for Medicinal Products for Human Use of the European Medicines Agency issued a positive opinion recommending approval of Abstral, in June 2008. ProStrakan and Orexo successfully launched Abstral in Sweden, the reference state, in August 2008 in their Nordic Joint Venture and ProStrakan plans further EU country launches as additional national licences are granted.

Commenting on the grant of the UK marketing authorisation for Abstral, Torbjörn Bjerke, President and CEO said:

“Abstral is an important product for cancer patients suffering from the debilitating effects of breakthrough pain. Its early UK approval means that ProStrakan can bring Abstral to their home market even earlier than had been planned, and they expect it to make a material contribution in 2009. This is a major achievement for the partnership between Orexo and ProStrakan and the royalty stream from Abstral will be important for Orexo in becoming a profitable pharmaceutical company. We look forward to expanding our successful working partnership in Europe and in the US in the near future.”

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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 in registration stage.

To date, Orexo has out-licensed the market rights for Abstral/Rapinyl for the US, EU and Japan markets and 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. Abstral/Rapinyl was approved in Europe on June 24, 2008. Orexo has established a Nordic sales force by entering into a joint venture with ProStrakan. Abstral was launched in Sweden during Q3 this year.

Orexo has its head office in Uppsala, Sweden 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 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.

www.prostrakan.com

Breakthrough Cancer Pain

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. 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