

# Press Release

**ProStrakan Group plc**

## **Abstral Receives Marketing Approval in France and Spain**

**Galashiels, Scotland, 02 March, 2009** – ProStrakan Group plc (LSE: PSK), the international specialty pharmaceutical company, announces that it has received Marketing Authorisations from the French regulatory authority (AFSSAPS) and the Spanish regulatory authority (AEMPS) for Abstral® (for breakthrough cancer pain).

These national approvals follow the receipt of a positive opinion recommending approval of Abstral from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in June 2008. ProStrakan now plans to launch Abstral in France and Spain in H2 2009 once pricing and reimbursement negotiations have been concluded with the relevant regulatory authorities.

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. ProStrakan has in-licensed the exclusive rights to this product in Europe and North America from the Swedish pharmaceutical company, Orexo AB.

ProStrakan commenced marketing Abstral in the UK and Germany in January 2009 following its launch in Sweden, in August 2008, through ProStrakan's joint venture for the Nordic countries with Orexo.

Commenting on the grant of the French and Spanish marketing approvals for Abstral, Dr Wilson Totten, Chief Executive of ProStrakan, said:

“These approvals mark further progress for the roll-out of this important product. We will now proceed with the launch of this product in France and Spain later this year and, as a result, make Abstral available for oncologists across most of Western Europe to prescribe.”

Ends

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**Notes to Editors:**

**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](http://www.prostrakan.com)

**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. More information can be found at [www.orexo.com](http://www.orexo.com)

## **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