

# Press Release

## ProStrakan Group plc

### In-licensing of European Rights to Rapinyl™ and Pre-close Period Trading Update

**Galashiels, Scotland – 21 December 2005** – ProStrakan Group plc (“ProStrakan” or “the Company”), the European specialty pharmaceutical company, announces today that it has signed an agreement to acquire, from January 2006, the European rights to Rapinyl, a drug in late stage clinical development for the management of breakthrough cancer pain in opioid tolerant patients, from the Swedish pharmaceutical company, Orexo AB (“Orexo”). The acquisition of these rights to Rapinyl, with its significant sales and margin potential, strong product differentiation and intellectual property position, will enable ProStrakan to build on its oncology supportive care franchise and leverage its specialist sales infrastructure in Europe.

ProStrakan also today provides a trading update prior to entering the Company's close period.

#### **In-licensing of Rapinyl**

Rapinyl is a new, fast-dissolving, sub-lingual tablet formulation of fentanyl, an opioid drug that has been used for many years to manage the sudden surges of pain (referred to as breakthrough pain) often experienced by patients suffering from cancer. The sub-lingual (under the tongue) formulation developed by Orexo brings rapid relief to patients in a highly convenient, user-friendly formulation.

It is estimated that there are in excess of 5 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). Using the safety and pharmacokinetic data compiled by Orexo to date, ProStrakan expects to submit Rapinyl for marketing approval in Europe in 2006.

Under the terms of the agreement with Orexo, ProStrakan will make an upfront cash payment of Euros 5 million in consideration for the European rights to Rapinyl, plus up to a further Euros 17 million on the achievement of certain regulatory and sales milestones, as well as royalties on future sales of Rapinyl.

Commenting on the in-licensing of Rapinyl, Dr Wilson Totten, Chief Executive of ProStrakan, said:

*"Rapinyl fits extremely well with our oncology supportive care franchise and has the potential to be one of the most important products in ProStrakan's portfolio. It is for precisely this type of product in-licensing opportunity that we have been building our pan-European sales infrastructure and it takes us significantly closer towards our goal of building a broadly-based, sustainably profitable European specialty pharmaceutical company."*

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*

## **Trading Update**

In a trading update today prior to entering the Company's close period, ProStrakan confirms that trading and cash levels are in line with the Board's expectations, with sales of Adcal D3®, the Company's osteoporosis drug, now commanding the leading market share position of its category by volume in the UK. Early sales of Rectogesic®, for the alleviation of chronic anal fissure pain, and Tostrex®, a gel for testosterone deficiency, both continue to make good progress following their launches earlier this year. The Mutual Recognition Procedure (MRP) in Europe for Rectogesic has recently commenced and is expected to be completed by the end of 2006. The MRP for Tostrex is expected to commence imminently and to be completed early in 2007.

The UK licence for the Company's branded bisphosphonate product, Ostalis, has been received but it is now expected that, once the appropriate regulatory approvals have been obtained, Ostalis will be commercialised in a combination pack with Adcal D3, rather than on its own as previously planned.

Finally, ProStrakan confirms that the first patients are expected to be treated in a Phase III trial of ProStrakan's transdermal anti-emetic patch to treat nausea and vomiting following chemotherapy, around the end of the year, in line with expectations.

Commenting on the trading update, Dr Wilson Totten, said:

*"This has been a successful first period for the Company following its flotation in mid-year. We have seen an encouraging start to the commercialisation of two important new products, Rectogesic and Tostrex, with the sales of Rectogesic being particularly pleasing, as well as continuing good growth in Adcal D3. The in-licensing of Rapinyl today further enhances our growing portfolio of specialist care products which address an unmet therapeutic need."*

## ***Enquiries:***

### **ProStrakan**

Wilson Totten, Chief Executive Officer  
Adrian Gardner, Chief Financial Officer  
David Watt, Corp Comms

**Tel: 01896 664000**  
**Tel: 01896 664000**  
**Tel: 01896 664103**

### **Financial Dynamics**

David Yates / Sarah Macleod

**Tel: 020 7831 3113**

A conference call for analysts will be held today at 2.30pm today. Please call Mo Noonan at Financial Dynamics for further details on 020 7269 7116.

## **Notes to Editors**

### **Breakthrough cancer pain**

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 called 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.

### **Rapinyl**

Rapinyl is a new, fast-dissolving, sub-lingual formulation of the opioid drug, fentanyl, for the management of acute pain in cancer patients. The product has been developed by the Swedish pharmaceutical company, Orexo AB. It was licensed in North America to Endo Pharmaceuticals in August 2004 and to Kyowa Hakko Kogyo Ltd. in Japan in January 2003. The technology behind Rapinyl is protected by patents in the US, Japan and throughout Europe.

### **ProStrakan**

ProStrakan Group plc is a rapidly growing international specialty pharmaceutical company engaged in the research, development and commercialisation of prescription medicines for the treatment of unmet therapeutic needs in major markets. The Company's therapeutic focus is on oncology supportive care, bone diseases, women's health and issues relating to the ageing male. Headquartered in Scotland, the Company's R&D facilities are situated in Romainville, near Paris, and in Galashiels in Scotland. EU-wide sales and marketing of ProStrakan's portfolio of products are principally handled by commercial subsidiaries based in the UK, France, Germany and Spain.

ProStrakan floated on the London Stock Exchange in June 2005. In September 2005, the Group announced interim results showing revenues up 78% to £16.5 million.

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

### **About Orexo**

Orexo is a product focused drug delivery company that develops proprietary pharmaceuticals to address areas of unmet therapeutic need. Orexo exploits its multidisciplinary capabilities to assess areas of therapeutic need that can be met by developing proprietary pharmaceuticals based on well documented pharmacologically active compounds that incorporate Orexo's proprietary drug delivery technologies.

The Company has commercialised one product, three product candidates in the clinical phase - where of one is out-licensed in North America and Japan - two product candidates in the formulation development phase and one project at an early research stage of development. Orexo is listed on the Stockholm Stock Exchanges O-list.

[www.orexo.com](http://www.orexo.com)