

Press Release

ProStrakan Group plc

Positive CHMP Opinion for Abstral (Rapinyl)

Galashiels, Scotland, 27 June, 2008 – ProStrakan Group plc (LSE: PSK), the international specialty 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 Abstral (formerly branded as Rapinyl), for breakthrough cancer pain. ProStrakan plans to launch Abstral in Sweden in Q3 2008 and, as a result of today's announcement, across Europe from the end of 2008.

Abstral 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 Rapinyl in Europe from the Swedish pharmaceutical company Orexo AB.

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.

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. ProStrakan has agreed, as a post-approval commitment, to supply the EMEA with final study reports and relevant analyses, when available, from the ongoing clinical programme currently being conducted in North America.

In March 2008, Abstral received a Marketing Authorisation for Sweden, which was the Reference Member State for the product during the decentralised procedure. As a result, Swedish clinicians will be the first in the world to be able to prescribe Abstral following its launch there, planned for Q3 2008, in a joint venture with Orexo AB.

Commenting on the positive opinion recommending approval of Abstral, Dr Wilson Totten, Chief Executive of ProStrakan, said:

“This is a very significant announcement for ProStrakan. Abstral will play a major role in the further development of our European business while, at the same time, providing clinicians with a patient-friendly formulation of fentanyl to prescribe to cancer patients suffering from breakthrough pain.

“The partnership with Orexo has proved to be very valuable for ProStrakan. We plan to launch this product within months in Sweden, where authorisation has already been achieved, and continue with its roll-out as further national Marketing Authorisations are received.”

Ends

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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Notes to Editors:

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 of its operations into the US. www.prostrakan.com

Orexo

Orexo AB 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 has out-licensed the market rights for Abstral for the US, the EU and Japan markets, the world-wide market rights for Sublinox (OX22) and OX-NLA, and launched an 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 its head office in Uppsala and is listed on the OMX Nordic Exchange Stockholm, Small Cap (ticker: ORX). www.orexo.com

Abstral

This product is a new formulation of fentanyl, a long-established opioid used for the management of episodes of severe breakthrough pain experienced by cancer patients who are already receiving opioid analgesics for their chronic pain.