



Press Release

ProStrakan Group plc

ProStrakan announces positive results from pivotal Phase III study on Sancuso™ (transdermal granisetron patch)

Results support regulatory filing in the EU and US

Galashiels, Scotland - 6 December 2006 – ProStrakan Group plc (LSE: PSK)(or ‘the Company’), the European specialty pharmaceutical company, today announces positive results from the pivotal Phase III programme on Sancuso™, its patented transdermal delivery system for the treatment of Chemotherapy Induced Nausea and Vomiting (CINV) in patients undergoing multi-day chemotherapy. Based on these results, ProStrakan expects to file regulatory submissions for Sancuso™ in the US and throughout the EU in the first half of 2007.

The study met its primary efficacy endpoint, demonstrating that a single application of the Sancuso™ patch prevented nausea and vomiting over the course of multi-day chemotherapy with efficacy comparable to repeat daily doses of oral granisetron. The safety profile for Sancuso™ shows no new or unexpected adverse events resulting from the transdermal delivery of granisetron compared to oral delivery. In particular, Sancuso™ was well tolerated at the application site.

Sales of 5-HT₃ antagonist products in the USA and the five largest European countries exceeded €2 billion in the year ending August 2006. This represented an increase of 12% compared to one year earlier (Source: IMS Health). ProStrakan owns the global intellectual property rights to Sancuso™ and the product forms an important part of the Company’s commercial strategy in Europe and the US. ProStrakan is in active discussions with several potential partners for the licensing of Sancuso™ in Japan.

Commenting on these results Dr Wilson Totten, CEO of ProStrakan, said:

“Nausea and vomiting is a major problem for cancer patients receiving chemotherapy. This is distressing to patients and can reduce the effectiveness of the treatment regimens employed. Sancuso™ is the first 5-HT₃ patch for CINV and offers the well-established safety and efficacy of granisetron in a simplified, patient-friendly product. Achieving multi-day protection from CINV by only a single application of the Sancuso™ patch avoids the need for multiple tablets or injections and provides reassurance of continuity of cover against CINV.

“For ProStrakan, these results exemplify the innovation and strength of the development skills in ProStrakan and represent a significant milestone towards achieving our aim of building our commercial presence in Europe and entering the US marketplace.”

There will be a conference call for analysts today at 9:30am. Please contact Mo Noonan at Financial Dynamics on +44 (0) 20 7831 3113. Presentation slides will be available on the Company website www.prostrakan.com

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About the Study

- Following discussion with US and EU Regulatory Agencies, the study was designed as the single pivotal Phase III trial to establish non-inferiority of transdermal granisetron (Sancuso™) compared to oral granisetron therapy.
- The design involved double dummy, double blind treatment with either Sancuso™ or oral granisetron in patients receiving moderately or highly emetogenic chemotherapy over the course of three, four or five days. The study randomised 641 patients in nine countries.
- The primary endpoint was non-inferiority of Sancuso™ compared to oral granisetron, and the efficacy of Sancuso™ was statistically demonstrated to be within a pre-defined non-inferiority margin compared to oral granisetron. This endpoint was studied during the course of the multi-day chemotherapy, including the 24 hours following the last chemotherapy dose.
- The variable designated for measuring primary efficacy was 'Complete Control', i.e. no vomiting or retching, no worse than mild nausea and no use of rescue medication during the course of the chemotherapy or in the following 24 hours. This endpoint is consistent with the EMEA draft "guideline on non-clinical and clinical development of medicinal products for the treatment of nausea and vomiting associated with cancer chemotherapy."
- A single pre-application of Sancuso™ provided 'Complete Control' in 59.8% of patients. The design of the study was such that statistical analysis of non-inferiority complies with the relevant guidelines.
- The safety profile of Sancuso™ was comparable with that for oral granisetron.

Notes to Editors

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. 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 handled by commercial subsidiaries based in the UK, France, Germany and Spain.

ProStrakan was listed on the London Stock Exchange in June 2005.

On 13th Sept 2006, the Company announced its Preliminary Results for the first half of 2006: revenues on continuing products increased by 28% over the prior period to £16.1 million; total gross profit increased by 14% to £9.9 million and retained loss increased by 6% to £14.9 million.

www.prostrakan.com