

Press Release

ProStrakan Group plc

ProStrakan Receives US FDA Approval for Sancuso

US launch planned before end of 2008

Galashiels, Scotland, 15 September, 2008 – ProStrakan Group plc (LSE: PSK), the international specialty pharmaceutical company, today announces that it has received approval from the US Food and Drug Administration (FDA) for Sancuso[®], ProStrakan's novel, patent protected transdermal patch for the prevention of chemotherapy-induced nausea and vomiting (CINV).

Key Points

- ProStrakan expects to launch Sancuso in the US before the end of 2008 – its first product launch in the US
- Sancuso, the world's first licensed transdermal 5HT₃ receptor antagonist product, will be launched into a market worth \$1.3 billion in the US alone
- As a patch, Sancuso offers cancer sufferers who are at risk of severe nausea & vomiting a new, patient-friendly treatment choice that is both non-invasive and non-oral
- Sancuso was developed in-house by ProStrakan – from inception to launch in five years
- Sancuso will be marketed by an exclusive US sales force, currently being established by ProStrakan in collaboration with NovaQuest (the partnering group of Quintiles)

Dr Wilson Totten, ProStrakan's Chief Executive Officer, said:

"FDA approval of Sancuso means that ProStrakan remains on track to launch its first product in the US, the world's largest pharmaceutical market, later this year. This is a very significant breakthrough, both for patients and ProStrakan.

"The launch will make Sancuso available for the first time to prevent nausea and vomiting in chemotherapy patients. Significant challenges persist in the prevention of CINV, which jeopardises the health of many chemotherapy patients and can deter them from continuing their cancer treatment.

"With peak sales potential in the order of \$100m each, Sancuso's US approval and that of Abstral in Europe are pivotal events in allowing ProStrakan to become profitable in the next two years.

"We plan to file two further New Drug Applications with the FDA in the US – for Fortigel and Cellegesic – in the coming months. The NDA for Rapinyl, for which we acquired the US rights in July, will follow in 2009."

ProStrakan has already established its US head office in Bedminster, New Jersey, and has recruited an experienced management team. Its US National Sales Manager is in place, together with seven Medical Science Liaison team-members, who have now been trained and will liaise with Oncologists and Oncology Nurses across the US. The Company will continue to work in collaboration with its US strategic partner, NovaQuest (the managed partnership group of Quintiles Transnational Corp.), to deploy its 67-strong national sales force.

Product Overview

Sancuso is a transdermal patch that delivers granisetron, an established 5HT₃ receptor antagonist, steadily into the bloodstream for up to seven days. Sancuso has been shown to be as efficacious as oral granisetron in preventing the side effects of nausea and vomiting in patients undergoing chemotherapy. Sancuso has the advantage of offering this protection through a single transdermal patch application, eradicating the need for repeated daily injections, thus reducing potential infection risk, or having to swallow

multiple pills on a repeated daily basis, which is often not possible in cancer patients due to oral mucositis.

The FDA approved Sancuso, for the prevention of CINV, based on the results of a multi-centre Phase III randomised, double-blind, double-dummy controlled study comparing the efficacy, tolerability and safety of Sancuso with once-daily oral granisetron (2 mg). The trial enrolled 641 patients who received moderately or highly emetic multi-day chemotherapy, and met its primary endpoint of non-inferiority of Complete Control of CINV compared to oral granisetron. Complete Control was defined as no vomiting and/or retching, no more than mild nausea and no rescue medication from first administration of Sancuso until 24 hours after the last day of chemotherapy. The most frequent adverse event was constipation.¹ As part of the approval, the Company has agreed to conduct certain post-approval clinical studies, including evaluations in children and the elderly.

Launch stocks of Sancuso are being manufactured by Aveva Drug Delivery Systems, Inc.TM, who specialise in the development and manufacture of transdermal drug delivery systems and will supply commercial stocks of Sancuso for ProStrakan on an ongoing basis.

Ends

¹ Steven M Grunberg et al. Phase III trial of transdermal granisetron patch (Sancuso) compared with oral granisetron in the management of chemotherapy-induced nausea and vomiting (CINV). MASCC Poster. June 18, 2007

There will be a conference call for analysts today (Monday 15 September) at 8.30am. Contact Mo Noonan, Financial Dynamics (+44 (0)20 7269 7116) for details.

For more information on this announcement, please contact:

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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