

# Press Release

**ProStrakan Group plc**

## **ProStrakan Announces FDA Acceptance of US Submission of Cellegesic™ (nitroglycerin) 0.4% Ointment**

**Galashiels, UK. 21<sup>st</sup> October 2009** – ProStrakan Group plc (LSE: PSK), the international specialty pharmaceutical company, today announces that the US Food and Drug Administration (“FDA”) has confirmed acceptance for review of ProStrakan’s refiling of its New Drug Application (“NDA”) for Cellegesic™ (nitroglycerin) 0.4% Ointment for the treatment of moderate to severe pain associated with chronic anal fissures. This refiling was made in response to the Action Letter issued by the FDA for Cellegesic on 7<sup>th</sup> July 2006.

Nitroglycerin-containing compounds are already recommended by a number of European and US clinical bodies for the pharmacological treatment of moderate to severe pain associated with chronic anal fissures, particularly as first line therapy, before resorting to surgery. Rectal use of nitroglycerin-containing compounds is well established in the US. Currently, these compounds are prepared at pharmacy outlets and there is therefore no assurance to the quality or strength of drug that the patient receives. Also, the safety and efficacy of these products have not been approved by the FDA. Subject to approval by the FDA, Cellegesic will be the first nitroglycerin product licensed in the US to address this unmet need.

In excess of 700,000 patients (Verispan PDDA MAT 03/08, ICD-9 565) in the US seek treatment for anal fissures each year. ProStrakan owns the global intellectual property rights to Cellegesic and the product forms an important part of the Company’s commercial strategy in Europe, where it has been approved and is marketed as Rectogesic, and in the

US, where ProStrakan currently markets Sancuso<sup>®</sup>, its novel, transdermal patch for the prevention of chemotherapy-induced nausea and vomiting (CINV), through its exclusive sales force.

Commenting on the US filing of Cellegesic, Dr Wilson Totten, Chief Executive of ProStrakan, said:

“The filing of Cellegesic is a further milestone in ProStrakan’s development and commercial expansion into the US. There are no currently approved products in the US for pain associated with chronic anal fissures and Cellegesic will fill this unmet need.”

Ends

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**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 located in Galashiels in Scotland. The company's development capabilities are centred in 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, Italy and other EU countries.

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