

# Press Release

## ProStrakan Group plc

### **ProStrakan announces commencement of recruitment in pivotal US Trials for Fortigel (Tostran) and Cellegesic (Rectogesic)**

**Galashiels, Scotland, 20 August, 2007** – ProStrakan Group plc (LSE: PSK), the specialty pharmaceutical company, today announces the enrolment of the first patients into two pivotal US trials in pursuit of FDA approval for its products: Fortigel (branded Tostran in most of Europe) and Cellegesic (branded Rectogesic in Europe).

Fortigel is a 2% testosterone gel used as replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical symptoms and laboratory analyses. Cellegesic is a rectal ointment for the relief of pain associated with chronic anal fissures. Both products have already been approved in Europe.

The “Fortify” trial for Fortigel is planned to enrol 140 hypogonadal male patients across 30 investigative sites in the US. The primary endpoint is based on the percentage of patients achieving normal blood testosterone levels and the pivotal protocol has been agreed by the FDA.

The “APT” (anal pain trial) with Cellegesic is planned to enrol 246 patients suffering from chronic anal fissures across 40 US and non-US sites. The primary endpoint of this placebo-controlled study is based on relief from anal fissure pain.

It is anticipated that top line results from both studies will be available in H1 2008 with NDA filing in H2 2008. Subject to FDA regulatory review, the US launch of both products is planned for 2009. If approved in the US, Cellegesic will be the first pharmacologic treatment indicated for the treatment of pain associated with chronic anal fissures.

**Commenting on the “Fortify” trial for Fortigel, Adrian Dobs MD, M.H.S., Professor of Medicine and Oncology at the Johns Hopkins University School of Medicine and principal co-ordinating investigator for the trial, said:**

“With the protocol now agreed with the FDA, we are hopeful that a positive outcome of this multi-centre study will result in a more patient-friendly treatment becoming available to American men with testosterone deficiency syndrome.”

**On the “APT” trial for Cellegesic, principal co-ordinating investigator, Scott Berry, M.D., FACS, Principal Investigator, Surgical Clinical Associates, Jackson MS, said:**

"This study should confirm that treating patients with Cellegesic will provide a rapid reduction in pain, an important clinical and quality of life measure for chronic anal fissure patients."

**Dr Wilson Totten, Chief Executive of ProStrakan, said:**

“Commencing these pivotal trials so soon after acquiring the US rights is a major achievement. With the US NDA approval process for Sancuso already under way and these two new US products in late stage development I am confident that, by 2009, we will have a substantial US business in place that will contribute significantly to the development and success of ProStrakan.”

Ends

**Further enquiries:**

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**Notes to Editors:**

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

**Fortigel**

Branded as Tostran, Itnogen or Tostrex in the EU, Fortigel is a patented transdermal testosterone gel that utilises a proprietary metered dose delivery system for testosterone replacement therapy in male hypogonadism.

The metered dose delivery system permits dose adjustment to individual patient requirements. Hypogonadism is frequently characterised by reduced libido, loss of muscle mass, bone density and diminished energy levels. Estimates show that around one in 10 men over 40 has clinically low testosterone.

**Cellegesic**

Branded as Rectogesic in the EU, Cellegesic is a 0.4% topical nitroglycerin ointment for the treatment of pain associated with chronic anal fissures. It is estimated that, at any time, between 500,000 and 800,000 in Europe alone experience anal fissures.