

Press Release

ProStrakan Group plc

ProStrakan Announces US Submission of Fortigel (testosterone) 2% Gel

Galashiels, Scotland, 5 May 2009 – ProStrakan Group plc (LSE: PSK), the international specialty pharmaceutical company, today announces the filing of its response to the Action Letter issued by the US Food and Drug Administration (“FDA”) on July 3, 2003 relating to ProStrakan’s New Drug Application (“NDA”) for Fortigel™ (testosterone) 2% Gel. The FDA has confirmed acceptance of this submission for review.

Fortigel is a patented 2% testosterone transdermal gel, which utilises a metered dose delivery system designed to permit accurate dose adjustment to individual patient requirements.

Estimates show that around 6%-12% of men over the age of 40 have clinically low testosterone (source: Araujo). This condition, known as male hypogonadism, is frequently characterised by reduced libido, loss of muscle mass, bone density and diminished energy levels. These symptoms can be alleviated through testosterone replacement therapy.

The development of Fortigel was initiated by Cellegy Pharmaceuticals Inc., who received a “not approvable” letter following the FDA’s review of the original NDA (submitted in 2002). ProStrakan took over the US rights for Fortigel in 2006 and conducted a new pivotal study to address the FDA’s questions. The design of the new study was agreed with the FDA under Special Protocol Assessment (SPA). The study involved 149 men aged 29-77 years, and in May 2008 the Company announced that the “Fortify” Phase 3 study had met all primary and secondary endpoints, demonstrating that the product was able to maintain adequate testosterone levels within all of the pharmacokinetic parameters agreed with the FDA.

In 2007, the total US testosterone market was \$660m. This represented an increase of 17% compared to one year earlier (source: IMS Health). US sales of testosterone gels in 2007 were \$545m, an increase of 18% compared to 2006 (source: IMS Health).

ProStrakan owns the global intellectual property rights to Fortigel and the product forms an important part of the Company's commercial strategy in Europe, and in the US, where ProStrakan currently markets Sancuso®, its novel, transdermal patch for the prevention of chemotherapy-induced nausea and vomiting (CINV), through a bespoke, 75-person sales force.

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

“The filing of Fortigel is a further milestone in ProStrakan's development and commercial expansion into the US. The US testosterone replacement market is significant and fast-growing and Fortigel is a unique product that is patient-friendly and has already proved to be popular with clinicians and patients in Europe. We plan to file two further products, Rapinyl™ and Cellegesic™, in the US in mid-2009.”

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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