

Press Release

ProStrakan Group plc

ProStrakan Receives Complete Response for Rectogesic from FDA

Galashiels, UK. 1st April 2010 – ProStrakan Group plc (LSE: PSK), the international specialty pharmaceutical company, today announces that it has received a Complete Response Letter from the US Food and Drug Administration (FDA) for its New Drug Application for Rectogesic[®] (0.4% nitroglycerin ointment) for the treatment of pain associated with chronic anal fissures.

The Complete Response letter identifies issues that would have to be addressed before re-submission, including the generation of additional clinical data. ProStrakan intends to meet with the FDA in the near future and discuss these requirements, and the potential timetable, in more detail.

Rectogesic (formerly known as Cellegesic in the US) is already approved in the EU and marketed by ProStrakan in all major European countries, where sales grew by 27% in 2009 to £8.1m. Rectogesic has also been out-licensed by ProStrakan to commercial partners in 34 countries worldwide.

Dr Wilson Totten, Chief Executive of ProStrakan, said:

“Even though this product is approved and being successfully marketed in the EU, it was always possible that further data may be required for a US approval. With this in mind, and with our current oncology focus in the US, we had not committed to commercialising Rectogesic ourselves in the US, nor had we made any partnering commitments. Consequently, we had not projected any US revenues from Rectogesic in our internal

budgets. However, the unmet medical need in the US for a prescription medicine for treating chronic anal fissure pain remains, and ProStrakan will evaluate viable future paths for Rectogesic in the US.

“ProStrakan’s strategy is built around a diversified portfolio of products across Europe, the US and through partnering, so our success is not dependent upon any single product. We remain firmly focused on growing the business profitably and revenue growth for the Group in the first three months of 2010 at constant currency has reached approximately 30%.

“With Abstral awaiting FDA approval and Fortesta scheduled for re-filing by Endo in mid 2010, we remain confident of further advances in our US strategy during 2010. We anticipate continued growth from Rectogesic in the EU and further out-licensing deals in non-core geographic areas.”

Other US Products’ Status

ProStrakan has a further product, Abstral, in registration in the US. Abstral is a new, sub-lingual (under the tongue) formulation of fentanyl, a long-established opioid used for the management of episodes of severe breakthrough pain experienced by cancer patients who are already receiving opioid analgesics for their chronic pain. ProStrakan submitted the New Drug Application (“NDA”) for Abstral to the FDA in August 2009. This has been accepted by the FDA which assigned Abstral a standard 10 month review period. If approved, ProStrakan plans to launch Abstral, through its US oncology sales force, in H2 2010.

In addition, Fortesta, ProStrakan’s transdermal testosterone gel that utilises a proprietary metered dose delivery system for testosterone replacement therapy in male hypogonadism (branded as Tostran in Europe), is expected to be re-filed in the US by ProStrakan’s partner, Endo Pharmaceuticals Inc., in mid 2010. In October 2009, the FDA issued a complete response letter to Endo requesting the re-analysis of some of the blood samples from the clinical study to ensure compliance with FDA analytical guidance.

Background on Rectogesic

A previous review of Rectogesic by the US FDA concluded with an “approvable” letter which included a request to perform another trial in patients to confirm efficacy in treating pain associated with chronic anal fissures. Following completion of this additional confirmatory study, the Rectogesic NDA was re-submitted in September 2009.

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 centered in Galashiels, UK, 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.

Further details about the business can be found at: www.prostrakan.com