Press Release

ProStrakan Receives FDA Approval for Rectiv™ for the Treatment of Moderate to Severe Pain Associated With Chronic Anal Fissures

Rectiv to be the only FDA approved prescription product for patients with this condition

Galashiels, UK, and Bedminster, NJ, USA. June 22, 2011 – ProStrakan Group plc, a subsidiary of Kyowa Hakko Kirin Co. Ltd., and an international specialty pharmaceutical company, today announces that it has received approval from the U.S. Food and Drug Administration (FDA) for Rectiv™ (nitroglycerin) Ointment 0.4% for the treatment of moderate to severe pain associated with chronic anal fissures. Rectiv will be the only FDA approved prescription product for patients with this condition.

"The pain associated with anal fissures can be unrelenting and debilitating. Prompt initiation of treatment by primary care practitioners, gynaecologists, gastroenterologists and surgeons alike is critical to a patient's wellbeing," said Scott Berry MD, FACS, colorectal surgeon and the principal investigator on one of Rectiv's clinical trials.

"Now we have an effective and easy-to-use topical ointment which allows grateful patients to resume their daily lives."

Anal fissures are fairly common, with approximately 700,000 people in the U.S. receiving a diagnosis or treatment for an episode each year. An anal fissure is a small tear in the skin that lines the anus, and can occur in a number of ways such as passing large or hard stools, straining during a bowel movement, or following an episode of diarrhea. When an anal fissure occurs, it typically causes severe pain and bleeding with bowel movements. Chronic anal fissure has been shown to impact significantly on patients' quality of life. An episode can take six to eight weeks to heal; and if healing does not occur then surgery may be required.[i-x]

Peter Allen, Chairman of ProStrakan, said:
"The market in the U.S. for a prescription medicine to treat chronic anal fissure pain is significant and, having successfully marketed this product in Europe for some years, we are pleased that it will now be made available to patients in the U.S."

"We will now evaluate the most efficient way of bringing this product to market and making it available as widely as is necessary."

ProStrakan expects Rectiv to be available in the U.S. in the first quarter of 2012. Marketed under the name Rectogesic®, the product is already approved in the EU and marketed by ProStrakan in all major European countries, where sales grew by 15% in 2010 to £9.3million ($14.4 million). The product has also been out-licensed outside Europe by ProStrakan to commercial partners in 34 countries worldwide.

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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 is a subsidiary of Kyowa Hakko Kirin Co. Ltd., the Japan-based global specialty pharmaceutical company.

ProStrakan's head office is located in Galashiels, Scotland. The company's development capabilities are centered in Galashiels and Bedminster, New Jersey, U.S. Sales and marketing of ProStrakan's portfolio of products are handled by commercial subsidiaries in the UK, U.S., France, Germany, Spain, Italy and other EU countries.

For more information please visit www.prostrakan-usa.com or www.prostrakan.com.

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