

# Press Release

## **ProStrakan Partners with Aptalis Pharma for Rectiv™ in the US**

**Galashiels, UK. 9<sup>th</sup> January 2012** – ProStrakan Group plc, a subsidiary of Kyowa Hakko Kirin Co. Ltd. (KHK), and an international specialty pharmaceutical company, today announces that it has signed an exclusive licensing and distribution agreement with Aptalis Pharma Inc (Aptalis) for Rectiv™ (nitroglycerin) Ointment 0.4%, for the treatment of moderate to severe pain associated with chronic anal fissure.

Rectiv will be the only FDA-approved prescription product in the United States for patients with this condition and is already marketed by ProStrakan as Rectogesic® in 20 countries worldwide including Europe where, in 2011, it is expected to have achieved €11m in sales.

Rectiv will be marketed exclusively by Aptalis in the US, where the company has a strong specialist gastrointestinal sales team. Aptalis plans to launch Rectiv as soon as possible in 2012. The availability of an FDA approved prescription product across the US is expected to make the therapy available to many more patients.

Under the terms of the agreement, Aptalis will make an upfront license fee payment to ProStrakan; a commercialisation payment; payments upon the achievement of certain sales milestones; and royalties on sales of Rectiv. ProStrakan will exclusively supply Rectiv to Aptalis in the US.

Tom Stratford PhD, Chief Executive of ProStrakan, said:

“Rectiv sits outside our core focus in the US, and that of our parent company, KHK, which is on oncology, immunology and nephrology, so it is strategically appropriate for ProStrakan to out-license Rectiv in the US. We are delighted to be partnering with such a highly regarded gastrointestinal specialty company as Aptalis for this important launch.

“Chronic anal fissure can cause significant pain for patients, and Aptalis’ team will work to get the message to physicians across the US of the launch of the only FDA approved prescription product for patients with this condition. This deal allows ProStrakan to continue to focus on our oncology franchise in the US, while ensuring that we fully capitalise on the potential of Rectiv.”

Frank Verwiel, M.D., President and Chief Executive Officer of Aptalis Pharma, said:

“This agreement will add strength and breadth to Aptalis’ portfolio of products. With Aptalis’ commercial expertise and infrastructure in the US, and our deep knowledge of and experience in the gastrointestinal space, we believe Aptalis is positioned to make a positive impact in the lives of patients diagnosed and treated for this condition.”

### **Important Safety Information**

Rectiv is contraindicated in patients taking phosphodiesterase type 5 (PDE5) inhibitors (eg, sildenafil, vardenafil, and tadalafil), which can potentiate the hypotensive effect of nitrate, and in patients with severe anemia, increased intracranial pressure, or known hypersensitivity to nitroglycerin, other nitrates and nitrites, or any components of the ointment. The most common adverse reactions are headache and dizziness. For full US prescribing information please see:

[www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/021359s000lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021359s000lbl.pdf)

## **About Anal Fissures**

An anal fissure is a small tear in the skin that lines the anus, which typically causes severe pain and bleeding with bowel movements. When anal fissures do not heal with interventions such as diet and lifestyle changes, fissures may become chronic. The pain associated with chronic anal fissure has been shown to have a significant impact on patients' quality of life. (Source: i – xi)

## **Enquiries:**

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## **Notes to Editors:**

### **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 in Scotland. The company's development capabilities are centered 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.

You can learn more about the business at: [www.prostrakan.com](http://www.prostrakan.com)

## **Sources:**

- i. Gearhart SL. Diverticular disease and common anorectal disorders. In: Fauci AS, et al. Harrison's Principles of Internal Medicine. 17th ed. New York, N.Y.: McGraw-Hill; 2008.
- ii. Lacy BE, et al. Common anorectal disorders: Diagnosis and treatment. Current Gastroenterology Reports. 2009;11:413.
- iii. Herzig D. Anal fissure. Surgical Clinics of North America. 2010;90:33.
- iv. Greenwald DA. Common disorders of the anus and rectum: Hemorrhoids and fissures. American College of Gastroenterology. <http://www.acg.gi.org/patients/gihealth/hemorrhoids.asp>. Accessed July 28, 2010.
- v. Yamada T, et al. Anorectal diseases. In: Yamada T, et al. Textbook of Gastroenterology. 4th ed. Philadelphia, Pa: Lippincott Williams & Wilkins; 2003.
- vi. Breen E, et al. Anal fissures. <http://www.uptodate.com/home/index.html>. Accessed July 28, 2010.

- vii. Anal fissure. American Society of Colon & Rectal Surgeons. [http://www.fascrs.org/patients/conditions/anal\\_fissure](http://www.fascrs.org/patients/conditions/anal_fissure). Accessed July 28, 2010.
- viii. Anal fissure. The Merck Manuals: The Merck Manual for Healthcare Professionals.
- ix. Gil J, et al. Screening for the effectiveness of conservative treatment in chronic anal fissure patients using anorectalmanometry. *International Journal of Colorectal Disease*. 2010;25:649.
- x. Klein MD, et al. Surgical conditions of the anus, rectum, and colon. In: Kliegman RM, et al. *Nelson Textbook of Pediatrics*. 18th ed. Philadelphia, Pa: Saunders Elsevier; 2007.
- xi. Rectiv prescribing information at FDA.gov:  
[http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/021359s000lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021359s000lbl.pdf)