

Press release, September 4, 2006

Orexo's licensing partner submits registration file for the pain product Rapinyl™

Orexo's European licensing partner ProStrakan Group plc. has announced submission of the registration file to obtain marketing approval on the European market for the pain product Rapinyl™ – Orexo's patented product for the treatment of breakthrough cancer pain. The Swedish Regulatory authority will be the rapporteur and coordinator for the registration process in Europe.

"ProStrakan's submission of the Rapinyl™ registration file is a big step towards the launch of our product in the European market place", says Zsolt Lavotha, President and CEO Orexo AB. "The fact that a registration file can be submitted for a product that we have developed in a few years, is another proof of the strength of Orexo's business model – to develop new, patented products in shorter time, with lower development costs and with low development risk. Furthermore, ProStrakan has a sales organisation covering key European markets which, in combination with recent market research study indicating a significant medical need for new pain products, are favourable conditions promising for a successful launch of Rapinyl™ in Europe" Lavotha said.

In addition to the up-front license fee payment of 5 M EURO (approximately 47 MSEK) received in January this year, and a milestone payment of 2 M EURO (approximately 19 MSEK) Orexo receives in connection with the Regulatory Filing indicated above, Orexo may receive other license fees and payments based on regulatory approvals and sales milestones, which total up to 15 M EURO (approximately 140 MSEK). When ProStrakan introduces Rapinyl™ on the European market, the agreement also provides for double-digit royalties upon commercial sales. Furthermore, the licensing agreement provides Orexo with the right to - in parallel with ProStrakan - market Rapinyl™ on the Nordic market.

Rapinyl™ is a product for the treatment of acute pain. The first indication is breakthrough pain in cancer. Rapinyl™ is based on Orexo's unique proprietary technology for sublingual administration, where a tablet is placed under the tongue and rapidly disintegrates into ordered mucoadhesive units of the active substance. This novel pharmaceutical preparation combines the properties of fast dissolution, quicker onset of action and predictable effect.

The marketing rights for Rapinyl™ are licensed to Kyowa Hakko Kogyo Co. Ltd for the Japanese market, to Endo Pharmaceuticals for the North American market and to ProStrakan Group plc for the European market.

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TO THE EDITORS**About Orexo**

Orexo is a pharmaceutical company that focuses on developing new pharmaceutical drugs within areas currently subject to considerable clinical needs. Orexo's products are based on existing pharmaceuticals and the company's patented drug-delivery technologies. Orexo applies its broad expertise in medicine and pharmacy to the further development of existing pharmaceutical substances. By combining well-documented compounds with its own patented drug-delivery methods and its unique expertise in "dry formulations" (for example, tablets), Orexo is able to develop new patented pharmaceuticals.

At present, the company has two products on the market, three under clinical development, one of which has been out-licensed in the US, Europe and Japan, two projects in the pharmaceutical formulation phase, and one project in an early development stage. Orexo has adopted an active intellectual property rights strategy and has, since its inception, built up an extensive patent portfolio to protect its products and technologies.

www.orexo.com

About ProStrakan

ProStrakan Group plc is one of Europe's fastest growing specialty pharmaceutical companies. ProStrakan is engaged in the research, development and commercialisation of prescription medicines for the treatment of unmet therapeutic needs in major markets. With R&D facilities based in the UK and France, the company also markets a range of products in major EU markets through its commercial operations based in the UK, Germany, France and Spain. ProStrakan is listed on the London Stock Exchange.

www.prostrakan.com

About drug delivery

The science of drug delivery can be summarized as the process of ensuring that the active substance in a pharmaceutical product is optimally delivered to the site of action. The demand for drug-delivery products is increasing rapidly due to the fact that these new pharmaceuticals can for example offer shorter time to onset of effect or improved safety profiles.

Many pharmaceutical products on the market today have shortcomings - for example, they are slow-acting, have side effects, must be administered frequently or perhaps can only be injected. This is why demand for technologies that can make already existing products more efficient is increasing rapidly. In 2004, industry sources estimated that sales of pharmaceutical products that utilize drug-delivery methods exceeded USD 79 billion, a figure that is expected to grow to USD 117 billion by 2009 (Datamonitor 2004).

About breakthrough pain

Breakthrough pain is defined as one or several daily, often intermittent flares ("breakthroughs") of pain that can occur even though a person is taking medications for regular pain control. Many patients with chronic cancer-related pain also experience episodes of breakthrough cancer pain.

About oral sublingual tablet formulation

Orexo's sublingual tablet technology combines fast disintegration and dissolution in the oral cavity with rapid, site-specific absorption of the active substance across the sublingual mucosa.

When administered, the tablet is placed under the tongue where it rapidly disintegrates into ordered mucoadhesive units of the active substance. Orexo believes that the rapid and reproducible absorption of the active substance makes the dosage form ideal for treatment of conditions requiring immediate onset of effect such as acute pain. The technology can also be applied to substances such as peptides, which cannot be absorbed from the gastrointestinal tract.