Press release, September 28, 2007

Orexo's Rapinyl™ nearing regulatory decision in Europe

Orexo´s European licensing partner ProStrakan Group plc, for the cancer breakthrough pain product Rapinyl™ on the European market, today announced that Rapinyl™ will be referred for review by the Committee for Medicinal Products for Human Use (CHMP) of the EMEA. Of the 25 member states involved in the EU Decentralised Procedure (DCP) for Rapinyl™, 21 consider this product to be approvable.

Without consensus among all 25 member states, the product will now be referred for review by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA), where a majority decision is sufficient to gain approval. The exact timings of the CHMP process are not yet clear, but it seems likely that the approval process will extend into 2008.

"While the process is taking some time, we remain confident in Rapinyl™ and its merits, and optimistic about regulatory approval in the not too distant future" said Zsolt Lavotha, CEO of Orexo.

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 which focuses on identifying suboptimal therapeutic characteristics of existing products and developing more efficient and effective delivery methods for them. By combining approved active substances with Orexo´s drug delivery technologies it is possible to significantly enhance their therapeutic value, such as providing quicker onset of action or ease of administration. This business model is aimed at bringing products to market faster with lower development risk and costs.

Orexo, which has its global headquarters and development laboratories in Sweden, currently operates across the world through development, licensing and distribution agreements in all major markets.

Orexo has a balanced portfolio with two products on the market, three in registration and/or late stage clinical phase and one in clinical phase I and one under formulation development.

Orexo is listed on the OMX Nordic List Mid Cap (ticker;ORX).
www.orexo.com

About ProStrakan
ProStrakan Group plc is a rapidly growing specialty pharmaceutical company 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 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.

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