

**Press release October 3, 2005**

## **Development milestone payment to Orexo after completed clinical study**

*Orexo AB has met the requirements for its first \$6.5 million development milestone payment from Endo Pharmaceuticals Inc., following the completion of a clinical trial of Rapinyl™ (OX 20) with positive outcome. In this trial, the dose range to be used in the next stage of development was established. Orexo's patented product Rapinyl™ (OX 20) is being studied for the management of breakthrough cancer pain. The two companies entered into a licensing agreement August 2004, which gives Endo Pharmaceuticals exclusive rights to develop and market Rapinyl™ (OX 20) for the North American market.*

“With the completion of this study, we now look forward to Endo, a market leader in pain management, conducting a Phase III trial programme supporting approval in the US for breakthrough pain in opioid tolerant cancer patients. This programme is planned to start later this year”, said Zsolt Lavotha, president and CEO of Orexo AB. “This accomplishment demonstrates the strength of our business.”

Rapinyl™ (OX 20) is an oral fast-dissolving sublingual tablet for the treatment of breakthrough cancer pain. It is based on Orexo's unique proprietary technology for sublingual administration where a fast-dissolving tablet is placed under the tongue and the active substance is absorbed over the sublingual mucosa. It is believed this novel pharmaceutical preparation could provide fast onset of action, predictable, consistent drug delivery and added convenience for patients suffering from breakthrough pain.

In return for the developing and marketing rights on the North American market, Orexo received an up-front payment of \$10 million. In addition to the above indicated milestone payment, Orexo may receive up to \$54.8 million, comprised of \$15.6 million in license fees and \$39.2 million in sales milestone payments. The agreement also provides for double-digit royalties upon commercial sales.

The Japanese marketing rights for Rapinyl™ (OX 20) were licensed to Kyowa Hakko Kogyo Co. Ltd in January 2003.

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***To the editors****About Orexo*

Orexo is a product focused drug delivery company that develops proprietary pharmaceuticals to address areas of unmet therapeutic need. Orexo exploits its multidisciplinary capabilities to assess areas of therapeutic need that can be met by developing proprietary pharmaceuticals based on well documented pharmacologically active compounds that incorporate Orexo's proprietary drug delivery technologies.

The Company has commercialized one product, three product candidates in the clinical phase – where of one is out-licensed in North America and Japan – two product candidates in the formulation development phase and one project at an early research stage of development.

[www.orexo.se](http://www.orexo.se)

*About drug delivery*

Drug delivery is about finding methods to make the active component of a drug to function in the optimal manner through new preparations or formulations. Many of the pharmaceuticals sold today have shortcomings – for example, they may be slow-acting, product side-effects, require frequent administration in high dosages, or perhaps can only be injected. This is why Orexo believes that the demand for new procedures that can enhance treatment efficiency is increasing sharply. Several best-selling prescription drugs in the U.S. has been improved through drug delivery.

*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.