

**Press release, June 26 2006**

## **Orexo presents positive study results for Sublinox™ (OX 22) at APSS (Associated Professional Sleep Societies)**

*Orexo presents positive study result for Sublinox™ (OX 22) at APSS (Associated Professional Sleep Societies) in Salt Lake City, USA. The results from the Sublinox (OX 22) study demonstrates fast onset of sleep, and maintained sleep during the night without “day-after” residual effects.*

The study – involving 21 healthy volunteers aged 18-40 years – was presented on June 21, 2006 at APSS (Associated Professional Sleep Societies) in Salt Lake City, USA. Sublinox™ (OX 22) is based on the well-documented substance zolpidem using Orexo´s sublingual technology, involving a tablet placed under the tongue for fast and effective uptake of the active substance over the sublingual mucosa. The result shows that Sublinox™ (OX 22) reduce the time to sleep onset by 30 percent compared to a conventional oral zolpidem tablet.

“The study confirms previous results and shows that Sublinox™ (OX 22), in addition to fast sleep induction, offers patients with sleeping disturbances good and maintained sleep without “day-after”-residual effects. In all, this gives Sublinox™ (OX 22) a competitive advantage in comparison with existing drugs, where time to sleep is longer and more unpredictable” said Zsolt Lavotha, President and CEO of Orexo AB.

Orexo initiates Phase III studies during 2006 to further document Sublinox™ (OX 22) unique clinical profile in preparation for registration and out-licensing. The phase III programme is expected to be completed in the first half of 2007 followed by registration application for the US and the EU during the second half of 2007.

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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 one product 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](http://www.orexo.com)

**Market for 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 Sublinox™ (OX 22)**

Sublinox™ (OX 22), a drug for the treatment of temporary insomnia, helps the patient fall asleep quickly and remain asleep throughout the night. It is based on Orexo's sublingual technology, involving a tablet placed under the tongue for fast and effective absorption of the active substance across the oral sublingual mucosa. The tablet contains the well-documented active substance zolpidem, one of the world's most widely used substances for treating insomnia.

The global market for insomnia was valued at 3.7 billion dollars in 2005 (Wood Mackenzie, December 2005). A large number of people suffering from insomnia – in the US the figure is estimated at 73 percent of insomnia sufferers – do not currently receive any treatment (Sanofi-Aventis 2005).

Sublinox™ (OX 22) has successfully completed the first clinical trial phases. A patent application has also been submitted in Europe.

**About insomnia**

Sleep is vital. It's during sleep the body recovers and the brain works with and stores information. Most part of all learning takes place during sleep. Besides, the stress hormone cortisol is reduced during sleep.

Lack of sleep leads to stress, which in turn leads to poorer sleep and can lead to anxiety, less pain resistance and as an extension, to depression. At loss of sleep the ability to among others, perform activities of daily life demanding attention, thinking or make decisions, are influenced. Other effects of lack of sleep are, for example, shifts of temper, difficulties with coordination and ache.