

**Press release, May 22, 2006**

## **Unique clinical profile for Orexo's product "OX 17" confirmed**

*Data supporting the clinical importance of Orexo's product 'OX 17' in the treatment of gastroesophageal reflux disease (GERD) was presented at the Digestive Disease Week (DDW) World Congress in Los Angeles on May 21, 2006. The data confirm that OX 17 combines rapid onset of effect with maintained efficacy during the treatment period.*

Acid reflux, i.e. "heartburn" and pain in the stomach, are some of the symptoms linked to gastroesophageal reflux disease. It is a common ailment in the Western world. Untreated, it could lead to inflammation of the gastric mucosa and, in the long term, also to cancer. Current treatments of acid reflux require either several days of treatment to obtain full effect, alternatively has effect only for a few days. The combined market for these two types of products, H<sub>2</sub> receptor antagonists (H<sub>2</sub> blockers) and proton pump inhibitors, amounted to USD 24.5 billion in 2005<sup>1</sup>.

Orexo's product OX 17 is based on a new therapeutic concept, combining H<sub>2</sub> blockers and proton pump inhibitors. The result is a fast onset of effect after the first dose and maintained efficacy over time. The unique efficacy profile of Orexo's product OX 17 has been demonstrated in 4 studies, where intra-gastric acid production have been measured in 45 healthy volunteers. OX 17 is considered as a potentially attractive treatment regimen for on-demand treatment of reflux disease and symptoms linked to this disease.

"Results from clinical studies confirm the unique profile of OX 17 and demonstrates that the positive effects can be achieved with different combinations of proton pump inhibitors and H<sub>2</sub> blockers", said Zsolt Lavotha, president and CEO of Orexo AB. "Thereby, we can confirm that the development of OX 17 is progressing according to plan, and that documentation further strengthening the product now will be carried out", he continued.

Based on these findings, Orexo is now verifying the documentation program with regulatory authorities and intends to initiate certain Phase III clinical studies during the second half of 2006. Patent for the combination concept has been filed in many countries and is pending in major markets.

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<sup>1)</sup> Astra Zeneca Annual Report 2005, Wood Mackenzie 2004

**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.

**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 OX 17**

The OX 17 product candidate targets the treatment of gastroesophageal reflux disease (GERD), a disease caused by recurrent acid reflux. OX 17 is based on a patent-pending combination of two well-documented substances – an H<sub>2</sub> receptor antagonist and proton pump inhibitor – in a formulation based on Orexo's patent-protected drug delivery technology.

OX 17 quickly and effectively impedes the stomach's production of hydrochloric acid, an essential step for effective symptom relief in patients suffering from reflux disease. The competitive advantages of OX 17 include the fast, effective and sustained inhibition of gastric acid production. Apart from symptom relief in GERD patients, OX 17 also has the potential to shorten the treatment of *Helicobacter pylori* infection.

The global market for H<sub>2</sub> receptor antagonists and proton pump inhibitors amounts to USD 24.5 billion. Patent for the combination concept has been filed in many countries and is pending in major markets.