

Press release September 2, 2008

## Orexo initiates clinical phase II program for OX914 - a new product candidate for the treatment of inflammatory airway diseases

**Uppsala, Sweden, September 2, 2008** – Orexo AB (OMX: ORX), the Swedish pharmaceutical company, announced today that the phase II program for the product OX914 has started. This is a new product candidate for the treatment of inflammatory airway diseases including asthma, COPD (chronic obstructive pulmonary disease) and rhinitis.

OX914 is a so called PDE4 inhibitor with an improved safety profile in development for the treatment of asthma, COPD and rhinitis.

The patients will be treated with OX914 in a disease model for inflammatory airway disease. Thirty six patients with seasonal allergic rhinitis will be given placebo or OX914 in doses of 15 or 50 mg for two weeks in a double blind 3-way cross-over study. Effects on nasal symptoms, inflammatory response, as well as safety and tolerability will be documented.

Dr. Torbjörn Bjerke, President & CEO of Orexo said: "This is Orexo's first NCE in Phase II. OX914 has the potential to be an important new product for the treatment of asthma, COPD and rhinitis with the improved safety profile in particular the lower frequency of nausea and vomiting compared to other PDE4 inhibitors in development. We look forward to results first half of 2009."

The global market for respiratory products is approx US\$ 17 billion.

**For more information, please contact:**

Torbjörn Bjerke, President and CEO, Orexo AB

Tel: +46 (0)708-66 19 90

E-mail: [torbjorn.bjerke@orexo.com](mailto:torbjorn.bjerke@orexo.com)

Claes Wenthzel, Executive Vice President & CFO, Orexo AB

Tel: +46 (0)708-62 01 22

E-mail: [claes.wenthzel@orexo.com](mailto:claes.wenthzel@orexo.com)

## TO THE EDITORS

### About Orexo

Orexo is a pharmaceutical company, focusing on development of new, patented drugs by combining well-documented substances with innovative technologies, and the development of new treatments for respiratory and inflammatory diseases.

Orexo has a broad and competitive late-stage product portfolio, including two marketed products, five products in clinical phase and two in registration stage.

To date, Orexo has out-licensed the market rights for Abstral®/Rapinyl™ for the US, EU and Japan markets and the world-wide market rights for Sublinox (OX22) and OX-NLA, and a out-license and research collaboration with Boehringer Ingelheim regarding the development of a new class of drugs to treat pain and inflammation. Abstral®/Rapinyl™ was approved in Europe on June 24, 2008. Orexo has established a Nordic sales force by entering into a joint venture with ProStrakan. Abstral® was launched in Sweden during Q3 this year.

Orexo has its head office in Uppsala, Sweden and is listed on the OMX Nordic Exchange Stockholm, Small Cap (ticker: ORX).

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

### About treatment of COPD and asthma

The aim of the program is to develop an orally active product that blocks the enzyme PDE4, present in many inflammatory cells. Several companies have, in clinical programs with different PDE4 inhibitors, shown positive treatment effects for COPD and asthma. However, no compound has reached the market so far, mainly because of the side effects, primarily nausea. OX914 has shown good effects in pre-clinical models of COPD and asthma, and clinical programs have not shown an increased frequency of nausea compared to placebo.