



**Press release - Uppsala, Sweden – October 30, 2012**

## **Orexo announces dosing of first patient with OX51 in phase II clinical trial on prevention of procedure-induced pain**

**Swedish specialty pharmaceutical company Orexo today communicated the start of the dose finding study for OX51 in patients undergoing prostate biopsy. Results from the study, which is a European study enrolling approximately 200 patients, will be available during the first half of 2013.**

OX51 is a novel breakthrough innovation from Orexo, which has been developed to meet the fast growing demand for efficient pain management during short-term surgical and invasive diagnostic procedures. OX51 is a sublingual formulation of alfentanil, based on the leading sublingual delivery technology developed by Orexo. The quick onset, short duration, rapid offset and convenient administration of OX51 make it suitable for prevention of pain during a multitude of procedures.

The market for short-term surgical and diagnostic procedures is large and growing with over 130 million procedures performed annually in the US and EU. The growth is driven by both improvement in technology, and a result of an increasing cost control, which propels a shift in such procedures from an in-patient/hospital setting towards an outpatient setting. This shift has created a major need for improving efficient pain management during the short-term surgical and diagnostic procedures without the full access to all resources otherwise found in a hospital.

“OX51 is yet another innovation from Orexo providing the first oral formulation of alfentanil and meeting a fast growing need from patients and health care providers. Feedback from doctors is universally positive to the product characteristics of OX51 and we move forward in the development of this highly innovative product with great confidence,” said Anders Lundström, CEO. “The dose finding study will enable Orexo to decide the best possible development strategy for phase III, which we expect to communicate during first half of 2013 once the trial has been completed”.

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### **About Orexo**

Orexo AB is an emerging specialty pharma company developing improved treatments using proprietary drug delivery technology. Orexo's expertise is within the area of reformulation technologies and especially sublingual formulations. The company has a portfolio of revenue-generating US and EU approved products currently marketed under licence and a pipeline of several reformulations of approved compounds for areas of unmet medical need. Orexo also has collaboration projects with several international pharma companies. Orexo AB with its headquarters in Sweden has 100 employees and is listed on NASDAQ-OMX. The largest shareholders are Novo A/S and HealthCap.

### **About OX51**

OX51, based on the active substance alfentanil, is being developed for the prevention of acute intensive pain in conjunction with care-related diagnostic or therapeutic procedures. OX51 is the first oral tablet formulation of alfentanil and building on the leading expertise in Orexo in sublingual formulation. OX51 product characteristics are very attractive for pain treatment during short procedures confirmed in market research among physicians and payers conducted by Orexo. The annual peak sales potential is estimated at around MUS\$ 250.

### **About Prostate Biopsy**

There are more than two million procedures of prostate biopsies performed annually in Europe and the US. Most of these procedures are performed in an outpatient setting. The diagnostic biopsy procedure is very standardized and normally involves use of local injection analgesia and use of anesthetic cream, but the resulting pain management is often inadequate and the procedure is often painful.

For more information about Orexo please visit [www.orexo.com](http://www.orexo.com)

*Orexo is required under the Financial Instruments Trading Act to make the information in this press release public. The information was submitted for publication at 1:30 pm CET on October 30, 2012.*