Press release

Orexo reports successful completion of OX51 phase II dose-finding study in prevention of procedure-induced pain

Uppsala, Sweden – August 28, 2013 – Orexo today announced the successful completion of a dose finding study for OX51 in patients undergoing prostate biopsy, as the study met its primary end-point of analgesic efficacy. The placebo controlled study, which tested sublingual administration of 3 different doses of OX51 and placebo, demonstrated a statistically significant dose response with respect to maximal pain experience during the biopsy procedure. Treatment with OX51 was safe and well-tolerated in all dose groups and no effects on local tolerability in any dose group were observed. In addition OX51 showed no effect on quantitative scales for assessment of sedation and drowsiness compared to placebo.

OX51 is a novel sublingual formulation comprising alfentanil, which has been developed to meet the fast growing demand for efficient pain management during short-term surgical and invasive diagnostic procedures. The quick onset, absence of sedation and drowsiness, short duration, rapid offset and convenient administration of OX51 makes it suitable for prevention of pain for a multitude of surgical and diagnostic 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. This 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 meeting a fast growing need from patients and health care providers. We estimate that the commercial potential of OX51 in short-term surgical and diagnostic procedures not requiring full anesthesia is substantial. With these positive results we will now consult the regulatory agencies to decide the best path forward for OX51, while ensuring that the organization remains focused on the launch of Zubsolv for opioid dependence in 2013, ”said Nikolaj Sørensen, President and CEO.

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About Orexo

Orexo AB is an emerging specialty pharma company with commercial operations in the United States and R&D in Sweden 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, with its headquarters in Sweden, is listed on NASDAQ-OMX. The largest shareholders are Novo A/S and HealthCap.

About OX51
OX51 is the first oral tablet formulation comprising alfentanil, which is being developed for the prevention of acute and intense pain episodes in conjunction with care-related diagnostic or therapeutic procedures. OX51 product characteristics are very attractive for pain treatment during shorter procedures according to market research among physicians and payers. The annual peak sales potential is estimated at around MUSD 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.

About the OX51-002 Dose-Finding Study
This is a double-blind, randomized, placebo controlled study in 180 patients in 17 selected sites in 4 different Europe countries undergoing elective prostate biopsy. The primary objective of this study is to evaluate the analgesic efficacy of OX51 in 3 different doses compared to placebo during the procedure in the chosen population.

For information about Orexo AB, please visit **www.orexo.com.**