Press release

First patient dosed in new study on long-term adherence to treatment of opioid dependence with Zubsolv®

Uppsala, Sweden – August 7, 2013 – Orexo today announces that the first patient has been dosed in a study designed to document the long-term effects of Zubsolv® on the retention and adherence to opioid replacement therapy. Other aspects that will be assessed and documented include opioid cravings, effects on withdrawal symptoms, tolerability and how treatment affects patients' quality of life. In addition, the study will enable Orexo to analyze the impact of Zubsolv on health economic parameters such as cost of treatment, clinical resource utilization and societal benefits.

Participation in this new study will be offered as a follow on-study to the patients who enter the ongoing studies on Zubsolv. These studies are focused on defining early treatment efficacy and treatment-adherence, when replacement therapy is initiated for opioid dependent patients. Approximately 750 patients are anticipated to be included across 100 centers in the US, and the study is expected to complete during 2014.

"With this study, which is one of three major clinical Zubsolv trials initiated this year, we are evaluating the long term aspects and potential long term benefits of treatment with Zubsolv. The study will not only establish patients' benefits during continued treatment with Zubsolv but the study has been designed to document the economic impact on the community by keeping more patients in treatment, which will be important in future discussions with payers in the US", explained Stuart Gitlow, President of American Society of Addiction Medicine and consultant to Orexo.

"Orexo is highly committed to improve the treatment of opioid dependence and with this study we will gain significant more insights into how Zubsolv will be used, the patient experience with the product during long-term use, and the impact that Zubsolv may have on patients quality of life. The outcome of the study will guide us in how we can improve our product and patient oriented services further, to ensure an optimal treatment of opioid dependence by use of Zubsolv," said Nikolaj Sørensen, president and CEO of Orexo.

For further information, please contact:
Nikolaj Sørensen, President and CEO of Orexo AB
Tel: + 46-703 50 78 88, Email: **nikolaj.sorensen@orexo.com**

Robert A DeLuca, President, Orexo US Inc
Tel: + 1 201 953 1349, E-mail: **robert.deluca@orexo.com**

About the Study

The study will be conducted with approximately 750 patients at 100 centres in the US. It is an un-controlled, open-label study. The participating patients will be analysed at seven visits during 24 weeks.

About Zubsolv®

Zubsolv is approved by the U.S. Food and Drug Administration (FDA) for Zubsolv. Zubsolv (buprenorphine/naloxone) sublingual tablet CIII, is indicated for use as maintenance treatment for people suffering from opioid dependence and should be used as part of a complete treatment with counselling and psychosocial support. Zubsolv is a novel sublingual formulation of buprenorphine and naloxone using Orexo's extensive knowledge in sublingual technologies. Through application of its proprietary technologies Orexo has increased the bioavailability of the active ingredient, accelerated dissolve time, reduced tablet size and improved taste. In a comparative acceptability study 9 out of 10 participants choose Zubsolv over the market leader Suboxone Film for a daily treatment. Zubsolv has the potential to be the first new entrant into a growing USD 1.5 billion market, with more than five million patients suffering from opioid dependence and where a majority of patients are not adequately treated today. Market potential for Zubsolv is at peak estimated at above USD 500 million in sales annually.

Orexo's proprietary technology relating to Zubsolv is protected by patents and patent applications in the US and other markets worldwide. Projected expiry dates for this IP range from 2019 to 2032.

About Orexo

Orexo 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 license and a pipeline of several reformulations of approved compounds for areas of unmet medical need. Orexo also has collaboration projects with several international pharmaceutical companies. Orexo, with its headquarters in Sweden, is listed on NASDAQ-OMX. The largest shareholders are Novo A/S and HealthCap.

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