Press release

First Patient Dosed in a New Clinical Study Designed to Assess Early Treatment Efficacy and Acceptability of Zubsolv®

Uppsala, Sweden – August 7, 2013 – Orexo AB announces that the first patient has been dosed in a new clinical study (ISTART; Induction, STabilization, Adherence, Retention Trial), designed to determine early treatment-efficacy and treatment-adherence to Zubsolv® (buprenorphine and naloxone) sublingual tablets in comparison to conventional buprenorphine/naloxone for the maintenance treatment of opioid dependence.

During 2012 Orexo completed an acceptability study, in which 89% of study participants, all healthy volunteers, favored Zubsolv over Suboxone® Film. The ISTART study is a natural next step in which the benefit of Zubsolv on retention, stabilization and adherence to treatment will be determined in opioid dependent patients.

The primary endpoint of the new ISTART study is retention in treatment at day fifteen following initiation of opioid replacement therapy. Treatment adherence is particularly important in the initial phases of addiction therapy, and prior research indicates that many patients do not tolerate or accept the previously used treatment modalities. Patients in the ISTART study will, after day 15, be followed in an extended observation period to explore long-term adherence to Zubsolv and collect clinical outcome data. The multi-center ISTART study will enroll more than 700 patients in the United States, and is one of the largest clinical trials undertaken in this field.

“Lack of adherence to the prescribed treatment of opioid dependence is a major issue, resulting in high level of personal suffering and expense for those affected. We know that many patients find characteristics of the existing treatment modalities to be an obstacle, and that this contributes to the drop-out rates from treatment previously observed. With Zubsolv we have developed an advanced sublingual tablet that addresses these obstacles through fast dissolve time, new menthol taste and small easy to administer tablet size”, say Stuart Gitlow, President of the American Society of Addiction Medicine and consultant to Orexo.

Nikolaj Sørensen, President and Chief Executive Officer of Orexo AB commented “ISTART is the third major study focused on treatment optimization within opioid dependence that Orexo is funding. These programs are undertaken to contribute further insights to how opioid replacement therapy may improve the lives of millions of patients suffering from opioid dependence in United States. Our research shows that the Zubsolv product features such as dissolve time and improved taste are important determinants for acceptability of sublingual treatments, and we look forward to expand this evidence base into treatment of opioid dependence through completion of the ongoing studies.”

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About the Study

The ISTART clinical study is expected to enrol approximately 700 patients in the US. It is a randomized, multi-center, non-inferiority study comparing Zubsolv® with Suboxone Film. Each enrolled patient will participate for 36 days and after completing this study the patients are invited to a follow-up study running for 24 weeks.

About Zubsolv®

Zubsolv (buprenorphine and naloxone) sublingual tablet CIII is approved by the U.S. Food and Drug Administration (FDA) as maintenance treatment for people suffering from opioid dependence. Zubsolv should be used as part of a comprehensive treatment plan which includes 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 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 EU and US 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, is listed on NASDAQ-OMX. The largest shareholders are Novo A/S and HealthCap.

For information about Orexo AB, please visit **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 08:15 am CET on August 7, 2013.