Press release

First patient dosed in new phase III study targeted towards a future clinical indication expansion for Zubsolv

Uppsala, Sweden – June 17, 2013 - Orexo AB announces today that the first patient has been dosed with Zubsolv in a phase III study for a new clinical indication for Zubsolv.

Currently all buprenorphine/naloxone combination products licensed in the US are indicated for maintenance treatment only. Following review by the United States Food and Drug Administration (FDA), Orexo has initiated a phase III study, which once completed successfully, will be the basis for an application to expand the Zubsolv label with a clinical indication that encompass induction of treatment. Zubsolv is a novel sublingual formulation of buprenorphine and naloxone, with projected approval for use in maintenance treatment of opioid dependence by the FDA by July 2013.

Approximately 300 patients will be included in this US trial, and the study is expected to be completed in early 2014.

Induction of opioid dependence treatment is currently limited to buprenorphine products not containing naloxone. With a successful study result and subsequent regulatory approval, physicians will be able to prescribe Zubsolv on-label for induction of opioid addiction treatment, and thereby facilitate an easier transition onto such treatment regimen for patients addicted to opioids.

”Orexo is working with the FDA to secure an on-time approval of Zubsolv for use in maintenance treatment. Once approved Zubsolv will be directed to the more than five million US citizens suffering from opioid dependence. Our new clinical research program will ensure that Zubsolv gains an important clinical practice differentiation and will ensure that patients can be offered Zubsolv from when they commence treatment for their opioid addiction”, states Nikolaj Sørensen, President and Chief Executive Officer of Orexo.

He continued by adding “Orexo is committed to take a leading role in optimizing treatment of opioid dependence in the US. We have previously conducted acceptance trials for Zubsolv, in which 89% of trial participants favored Zubsolv over the conventional buprenorphine treatment modalities for opioid addiction, to understand how our formulation technology could aid in improving acceptability of buprenorphine treatment. The current clinical research initiative to expand the future labeled indication for use of Zubsolv is a logical next step, and we look forward to report on the data in the first half of 2014”

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About the Induction Study
The study is conducted with approximately 300 patients in the US. It is a randomized, multi-center, blinded, parallel group, active-controlled non-inferiority study comparing Zubsolv with buprenorphine. It is expected to run until early 2014.

About Zubsolv
Zubsolv is a novel sublingual formulation of buprenorphine and naloxone using Orexo's extensive knowledge in sublingual technologies. Zubsolv is intended for maintenance treatment of people suffering from opioid dependence. 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.

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**