Press release – Uppsala, Sweden – November 19, 2012

Orexo announces that Zubsolv™ has been accepted for review by the U.S. Food and Drug Administration (FDA)

FDA has informed Orexo that the Zubsolv New Drug Application (NDA) has been accepted for review, and that the Prescription Drug User Fee Act (PDUFA) action date will be July 6, 2013.

Orexo submitted the application for approval of Zubsolv on September 6, 2012. Following a preliminary assessment of completeness, the application is now entering the substantive review stage. Orexo expects Zubsolv to be approved 10 months after submission to the FDA, in July 2013. The launch of Zubsolv is planned for September 2013.

"Today's notice from the FDA is yet another step for Orexo towards becoming a fully integrated specialty pharmaceutical company with a US commercial presence. We have a good chance of becoming the first company to offer an alternative treatment option to Suboxone®, which is today the leading product in the US market for the treatment of opioid dependence," says Anders Lundström, Orexo's President and CEO.

Opioid dependence is increasingly recognized as a major health problem in the US, with over two million Americans affected, costing society an estimated USD 25 billion in related health care costs. Zubsolv will, once approved by the FDA, be directed towards authorized specialized prescribers. The opioid dependence market currently served with Suboxone is estimated to reach sales of USD 1.5 billion in 2012 and continues to display steady growth of more than 15 percent per year.

To differentiate Zubsolv from competitors and maximize the commercial potential, comprehensive clinical development and product life cycle management programs have now been initiated. The primary focus of these programs is to fully explore and document the therapeutic potential of Zubsolv in initiating treatment of opioid dependence, and to document treatment adherence and patient experiences during maintenance treatment with Zubsolv. In addition, Orexo will be completing documentation of further dose strengths as well as providing one additional flavour of Zubsolv to complement the current product offering.

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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, is listed on NASDAQ-OMX. The largest shareholders are Novo A/S and HealthCap.

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 resulting in a preference of Zubsolv in comparison with Suboxone tablet. Zubsolv has the potential to be the first new entrant into a USD 1.3 billion market, with more than two 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 USD 500 million in sales annually.

For more information about Orexo 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 08:00 am CET on November 19, 2012.