Press release

Orexo provides update on reimbursement and launch preparations for Zubsolv®

Uppsala, Sweden – September 5, 2013 – Orexo announced today that the preparations for launch of Zubsolv® (buprenorphine and naloxone) sublingual tablets (CIII) has progressed according to plans and that Zubsolv will be available in pharmacies across the U.S. from September 16. Zubsolv received approval from the U.S. Food and Drug Administration (FDA) in July 2013 for the maintenance treatment of opioid dependence, as part of a complete treatment plan including counseling and psychosocial support.

Market access continues to be a key focus area for Orexo and negotiations with payers are progressing as anticipated. Zubsolv will at launch be reimbursed in more than 70% of the current market for opioid replacement therapy. Zubsolv will be launched with list-pricing comparable to Suboxone film, but with an enhanced patient assistance through co-pay support initiatives. Interest in Zubsolv among the largest commercial plans is strong. For instance, a rebate agreement is signed with CVS Caremark which allows its commercial PBM clients to qualify for rebates if the client places Zubsolv in a preferred formulary position. Earlier this year CVS Caremark announced that effective January 1st 2014, Suboxone Film has been removed from the formularies for its commercial clients who participate in the formulary drug exclusion program. For those clients, Zubsolv will be the only single source brand drug covered. Orexo plans to provide further updates on developments in the US reimbursement landscape for Zubsolv in relation to the quarterly earnings releases.

Orexo has during the past 8 weeks finalized the establishment of the commercial infrastructure for launch of Zubsolv in the United States. The supply chain has inventory to meet market demands, and Zubsolv tablets will at launch be available through all leading wholesalers and in more than 11.000 pharmacies. Zubsolv is exclusively being supplied in specially designed child-resistant packages, in which the individual tablets are wrapped in a special blister foil that optimally protect children against accidental exposure. Zubsolv will at launch be the only buprenorphine containing product, which is commercialized with the highest degree of child resistant packaging protection (F1-grade).

The previously announced US commercial partnership with Publicis Touchpoint Solutions is fully operational and the commercial organization has been staffed with highly competent and talented people. The sales teams have been operational in the most important districts since early August and the sales representatives have engaged with many key prescribers prior to launch of Zubsolv. The prescribers recognize the need for access to additional choices of treatment, and the feedback obtained indicates a high unprompted awareness of both Zubsolv and Orexo. To their support, Orexo has launched a patient support program (**www.rise-us.com**), a Zubsolv home page (**www.zubsolv.com**) and a toll free number **1-888-ZUBSOLV**, all developed for the US market.

“We are now entering the most exciting time in the history of Orexo. Having worked closely with my team in the US and our partner Publicis Touchpoint Solutions during the summer, I am confident we are headed for a successful launch. Based on our recent study, in which 9 out of 10 participants preferred Zubsolv versus the market leader, the strong feedback from prescribers who explicitly

demand alternatives for patients, and our improving market access position, my confidence in that sales of Zubsolv can exceed $500M within 3 years after launch has been strengthened. I am pleased with the progress in market access achieved since approval of Zubsolv, and remain certain that we will have a comprehensive and competitive market access position by the end year of this across commercial and public payer segments" said Nikolaj Sørensen, President and CEO.

As a result of the positive response in the US and growing interest in Orexo, a process has been initiated to improve access for US investors to trade in the Orexo share by establishment of a sponsored level 1 American Depositary Receipt (ADR) program. Further details pertaining to this will be provided at a later stage.

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About Zubsolv
Zubsolv® (buprenorphine and naloxone) sublingual tablet (CIII) is indicated for the maintenance treatment of opioid dependence and should be used as part of a comprehensive treatment plan, which includes counseling and psychosocial support. Treatment should be initiated under the direction of physicians who are certified under the Drug Addiction Treatment Act of 2000, and who have been assigned a unique identification number ("X" number).

Zubsolv sublingual tablets deliver more buprenorphine to the bloodstream, allowing patients to use a lower dose and thereby reducing the amount of available drug for potential misuse and diversion. The naloxone component of Zubsolv further reduces the potential for IV misuse and diversion.

Zubsolv sublingual tablet can be abused in a manner similar to other opioids, legal or illicit. Clinical monitoring appropriate to the patient's level of stability is essential. Liver function should be monitored before and during treatment. Children who take Zubsolv sublingual tablet can have severe, possibly fatal, respiratory depression. Emergency medical care is critical. Keep Zubsolv sublingual tablet out of the sight and reach of children. Zubsolv will be the only opioid dependence treatment that is available in the highest level of child resistant unit dose F1 packaging, thereby further reducing the chance of unintended pediatric exposure.

Adverse events commonly observed with the sublingual administration of buprenorphine/naloxone sublingual tablets during clinical trials and post-marketing experience are headache, nausea, vomiting, hyperhidrosis, constipation, signs and symptoms of withdrawal, insomnia, pain and peripheral edema.

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

For information about Zubsolv, please visit **www.zubsolv.com**

About Orexo AB
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 and commercial operations in the United States. The company is commercializing its

proprietary product, Zubsolv® (buprenorphine and naloxone), for maintenance treatment of opioid dependence, in the United States. Zubsolv is a novel sublingual formulation of buprenorphine and naloxone using Orexo's extensive knowledge in sublingual technologies. Orexo has a portfolio of two approved and revenue generating products currently marketed under license in the EU and US. Orexo's development expertise is within the area of reformulation technologies and especially sublingual formulations. 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.**

Zubsolv is a new, advanced formulation of buprenorphine and naloxone, approved for maintenance treatment of opioid dependent patients, which provides fast dissolve time, small tablet size, a new menthol flavor and a higher bioavailability than current marketed products.

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 09:30 am CET on September 5, 2013.