

## Press release

# Orexo announces new partner for the commercialization of Zubsolv<sup>®</sup> in the United States.

**Uppsala, Sweden – May 20, 2014** – Orexo AB announces a new partnership between Orexo US, Inc. and inVentiv Health for the commercialization of Zubsolv in the US. The new partnership agreement replaces existing contracts and will become effective July 1<sup>st</sup>, 2014 and has a three year term.

In the new partnership, Orexo takes the leadership and control of all commercial functions to ensure the efficient and agile governance of the commercialization of Zubsolv. Consequently Orexo will directly employ the sales managers and take over leadership and day to day management of field-based promotional activities. The new partner inVentiv Health will take responsibility of employing and supporting the individual sales representatives.

The new partnership calls for Orexo to cover direct sales force expenses from inVentiv Health. As a consequence of the new partnership structure the expenses for the sales organization will be reported as a selling expense from the second quarter this year. There will be a limited one-time transition expense reported in the second quarter, associated with the change of partner. From the third quarter 2014, there will be no further expenses related to the previous partnership.

"With this new partnership structure Orexo will increase the control of the sales operations to ensure Zubsolv gains the attention and focus required to maximize the potential. With the new structure in place we will be able to act much more swiftly in the market and we see this as a natural next step in the evolution of Orexo and an important driver of growth" says Nikolaj Sørensen, Chief Executive Officer of Orexo AB.

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### **About Orexo AB**

Orexo AB is a specialty pharma company with commercial operations in the United States and R&D in Sweden developing improved treatments using proprietary drug delivery technology. The company is commercializing its proprietary product, ZUBSOLV® (buprenorphine and naloxone), in the United States for maintenance treatment of opioid dependence. 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, US and Japan. 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, please visit www.orexo.com

#### About inVentiv Health

inVentiv Health, Inc. is a life science knowledge and services company purpose-built for the new healthcare marketplace. inVentiv has created a new model by converging a vast range of essential services to fully align with our client's development and commercialization goals. With more than 12,000 employees supporting clients in 70 countries, our global scale and broad expertise make us an attractive strategic partner for companies seeking to get medicines to patients in a complex operating, regulatory and reimbursement environment. inVentiv Health's clients include more than 550 life sciences companies, including all 20 of the largest biopharmaceutical companies in the world. inVentiv Health, Inc. is privately owned by inVentiv Group Holdings, Inc., an organization sponsored by affiliates of Thomas H. Lee Partners, L.P., Liberty Lane Partners and members of the inVentiv management team. inVentiv Health transforms promising ideas into commercial reality for the financial success of our clients and the delivery of better treatments to patients worldwide.

For more information, visit www.inVentivHealth.com.

### **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 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 tests should be monitored before and during treatment. Children who take ZUBSOLV sublingual tablets can have severe, possibly fatal, respiratory depression. Emergency medical care is critical. Keep ZUBSOLV sublingual tablets out of the sight and reach of children.

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.

Further information on Zubsolv can be found at www.zubsolv.com.



### **IMPORTANT SAFETY INFORMATION**

- Keep ZUBSOLV in a secure place away from children. If a child accidentally takes ZUBSOLV, this is a medical emergency and can result in death. Get emergency help right away
- ZUBSOLV can cause serious and life-threatening breathing problems. Call your doctor right away or get emergency help if (a) you feel faint, dizzy, or confused; (b) your breathing gets much slower than is normal for you; (c) you feel sleepy and uncoordinated; (d) you have blurred vision; (e) you have slurred speech; (f) you cannot think well or clearly; or (g) you have slowed reflexes and breathing. In an emergency, have family members tell the emergency department staff that you are physically dependent on an opioid and are being treated with ZUBSOLV
- The most common side effects of ZUBSOLV include: headache, drug withdrawal syndrome, nausea, decrease in sleep (insomnia), vomiting, pain, increased sweating, swelling of the extremities, and constipation. Tell your doctor about any side effect that bothers you or that does not go away
- Do not switch from ZUBSOLV to other medicines that contain buprenorphine without talking with your doctor. The amount of buprenorphine in a dose of ZUBSOLV is not the same as the amount of buprenorphine in other medicines that contain buprenorphine.

  Your doctor will prescribe a starting dose of buprenorphine that may be different than other buprenorphine-containing medicines you may have been taking
- ZUBSOLV contains an opioid that can cause physical dependence. Do not stop taking ZUBSOLV without talking to your doctor. You could become sick with uncomfortable withdrawal signs and symptoms because your body has become used to this medicine. Physical dependence is not the same as drug addiction. ZUBSOLV is not for occasional or "as needed" use
- An overdose, and even death, can happen if you take benzodiazepines, sedatives, tranquilizers, or alcohol while using ZUBSOLV. Ask your doctor what you should do if you are taking one of these. You should not drink alcohol while taking ZUBSOLV, as this can lead to loss of consciousness or even death
- Do not inject ("shoot-up") ZUBSOLV. Injecting ZUBSOLV may cause life-threatening infections and other serious health problems. Injecting ZUBSOLV may cause serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings
- Before taking ZUBSOLV, tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements



- Before taking ZUBSOLV, tell your doctor if you are pregnant or plan to become pregnant. It is not known if ZUBSOLV will harm your unborn baby. If you take ZUBSOLV while pregnant, your baby may have symptoms of withdrawal at birth. Talk to your doctor if you are pregnant or plan to become pregnant
- Before taking ZUBSOLV, tell your doctor if you are breastfeeding or plan to breastfeed. ZUBSOLV can pass into your breast milk and may harm the baby. Talk to your doctor about the best way to feed your baby if you take ZUBSOLV. Monitor your baby for increased sleepiness and breathing problems
- Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how ZUBSOLV affects you. Buprenorphine can cause drowsiness and slow reaction times. This may happen more often in the first few weeks of treatment when your dose is being changed, but can also happen if you drink alcohol or take other sedative drugs when you take ZUBSOLV
- ZUBSOLV is a controlled substance (CIII) because it contains buprenorphine, which can be a target for people who abuse prescription medicines or street drugs. Keep your ZUBSOLV in a safe place to protect it from theft. Never give your ZUBSOLV to anyone else; it can cause death or harm them. Selling or giving away this medicine is against the law
- To report negative side effects associated with taking ZUBSOLV, please call 1-888-982-7658. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088

Please see full Prescribing Information and Medication Guide for ZUBSOLV.

Orexo AB (publ) discloses the information provided herein pursuant to the Financial Instruments Trading Act and/or the Securities Markets Act. The information was submitted for publication at 08:00 am CET on May 20, 2014.