Press release

FDA approves two higher dosage strengths of ZUBSOLV®

Uppsala, Sweden – December 12, 2014 – Orexo AB (publ) announces today that it has received approval from the U.S. Food and Drug Administration (FDA) of two higher dosage strengths of ZUBSOLV (buprenorphine/naloxone CIII sublingual tablet) for maintenance treatment of opioid dependence. The new dosage strengths are 8.6 mg/2.1 mg and 11.4 mg/2.9 mg buprenorphine/naloxone CIII sublingual tablets. The 8.6 mg/2.1 mg dosage strength is expected to be launched early 2015 and the 11.4 mg/2.9 mg strength later in 2015.

The new dosage strengths complement the existing strengths of 5.7 mg/1.4 mg and 1.4 mg/0.36 mg tablets and enable patients to receive their optimal dose in one tablet. The new strengths are made with the advanced, proprietary sublingual tablet formulation in ZUBSOLV providing higher bioavailability, a fast dissolve time, small tablet size, and menthol flavor.

"Orexo remains fully committed to advancing the treatment of opioid dependence. During the summer, we received positive data from the largest clinical trials ever conducted in this disease area. Today, we are proud to announce that the FDA has approved two additional dosage strengths of ZUBSOLV. These higher dosage strengths will allow more patients to get the right dosage in only one tablet and thus reduce the need to combine different dosage strengths. This will improve patient convenience and adherence while reducing their out-of-pocket cost as only one co-pay will be required," said Nikolaj Sørensen, CEO and President of Orexo AB.

The advanced formulation provided by ZUBSOLV meets the needs expressed by patients, such as improved taste and fast dissolve time. Meeting patient needs may have the potential to improve patient adherence, thus reducing relapse rates and improving successful patient outcomes. ZUBSOLV is the only opioid dependence treatment option available in the highest level of child resistant, unit dose, F1 packaging, designed to reduce the chance of unintended pediatric exposure.

For further information, please contact:
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About Orexo AB

Orexo is a specialty pharma company with commercial operations in the United States and R&D in Sweden developing improved treatments using proprietary drug delivery. The company is commercializing its proprietary product, ZUBSOLV® sublingual tablets, for maintenance treatment of opioid dependence, in the United States. The ZUBSOLV sublingual tablet is a novel 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 US, EU and Japan. Orexo AB, with its headquarters in Sweden, is listed on Nasdaq Stockholm Exchange (STO: ORX) and its American Depositary Receipts (ADRs) trade on the OTCQX marketplace in the U.S. under the symbol, "ORXOY". The largest shareholders are Novo A/S and HealthCap.

For information about Orexo, please visit **www.orexo.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 8:30am CET on December 12, 2014.