



Press release

Orexo Enters an Exclusive Reimbursement Agreement with UnitedHealth Group and OptumRx for ZUBSOLV®

Uppsala, Sweden – March 12, 2014 – Orexo AB, the manufacturer of ZUBSOLV® (buprenorphine and naloxone) sublingual tablets (CIII), announced a multi-year agreement with UnitedHealth Group® and OptumRx® providing preferred coverage and reimbursement of ZUBSOLV®.

Under the agreement, ZUBSOLV will be given preferred, Tier 2 brand status on UnitedHealth Group commercial employer and individual formularies managed by OptumRx for the maintenance treatment of opioid dependence through June 30, 2014. Beginning on July 1, 2014 ZUBSOLV will become the only buprenorphine/naloxone combination product on all of UnitedHealth's closed and highly managed health plan formularies, inclusive of all brand and generic formulations.

"Orexo's mission is to increase access to medication-assisted treatment plans, help reduce relapse rates and improve successful patient outcomes – all critically important in the face of the growing opioid dependence epidemic in the US," said Robert DeLuca, R.Ph., President, Orexo U.S., Inc. "Our long term strategic partnership with UnitedHealth Group and OptumRx enables us to assist a greater number of patients who are incorporating a treatment option such as ZUBSOLV into their recovery plans."

"Orexo is dedicated to broadening the market access position for ZUBSOLV and this agreement with UnitedHealth Group and OptumRx is an important step in that direction. It is a major achievement and endorsement as health insurers with a firm control over their formularies recognize ZUBSOLV as the preferred buprenorphine/naloxone formulary product for the maintenance treatment of opioid dependence" said Nikolaj Sorensen, CEO and President of Orexo.

ZUBSOLV is an advanced sublingual tablet formulation for maintenance treatment of opioid dependence with high bioavailability, a fast dissolve time, small tablet size, and menthol flavor. The advanced formulation provided by ZUBSOLV was specifically designed to meet the needs expressed by patients. Meeting patient needs may have the potential to improve patient adherence, thus reducing relapse rates and improving successful patient outcomes. It 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:

Nikolaj Sorensen, President and CEO, Orexo AB

Tel: +46-703 50 78 88, E-mail: ir@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.

About Orexo

Orexo is a specialty pharmaceutical 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 Orexo U.S., Inc.

Orexo U.S., Inc. is a subsidiary to Orexo AB, a specialty pharmaceutical company. The subsidiary markets improved treatments for opioid dependence using proprietary drug delivery technology. To receive more information, please contact Orexo at 1-855-ZUBSOLV.

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 08:45 am CET on March 12, 2014.