Press release

Orexo submits application to FDA for expanded label of ZUBSOLV®

Uppsala, Sweden – October 13, 2014 – Orexo AB (publ) announces today that it has submitted an application to the U.S. Food and Drug Administration (FDA) for an expanded label of ZUBSOLV (buprenorphine/naloxone CIII sublingual tablet) to include initiation of treatment for opioid dependence. Orexo anticipates a potential approval of the expanded label during the third quarter 2015.

The application for initiation of treatment is supported by the data from the ISTART and OX219-007 studies. In the full dataset, Orexo found no difference when comparing ZUBSOLV and generic buprenorphine monotherapy, when used as treatment for the induction of buprenorphine maintenance therapy[1].

"The FDA submission constitutes an important milestone for ZUBSOLV. Today we take an important next step in the evolution of the product, applying for a new indication and expanded label. A label including initiation of treatment will enhance product differentiation and enable Orexo to educate physicians in how to optimally use ZUBSOLV from the first day of treatment." said Nikolaj Sørensen, CEO and President of Orexo AB.

In a survey performed by Orexo among DATA2000 waivered physicians, who are less active in treating opioid dependent patients, initiation of treatment was cited as the main challenge when treating patients for opioid dependence by more than 40-percent of the respondents. 58-percent of the physicians said more education would be a main driver for increasing their use of buprenorphine based treatment. An induction label would allow Orexo to customize the education to meet the specific needs of these physicians to increase their comfort in treating patients suffering from opioid dependence.

Nikolaj Sørensen, CEO and President of Orexo AB, noted "Many patients suffering from opioid dependence have difficulties in finding waivered physicians, with an expanded label Orexo can take an active role to encourage and educate the waivered, but not active, prescribers in initiation of treatment and improve access to treatment for patient suffering from opioid dependence."

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[1] Results from ISTART (OX219-006) and OX219-007 studies are available in a press release June 23, 2014 on www.orexo.com

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 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 08:00 am CET on October 13, 2014.