U.S. FDA Approves ZUBSOLV® for Induction of Buprenorphine Maintenance Therapy in Patients Suffering from Opioid Dependence

Uppsala, Sweden – August 11, 2015 - Orexo AB (publ) announced today that the U.S. Food and Drug Administration (FDA) has approved ZUBSOLV® (buprenorphine/naloxone CIII sublingual tablet) for induction of buprenorphine maintenance therapy in patients with opioid dependence. The approval expands on the current indication for ZUBSOLV, originally approved by the U.S. FDA on July 3, 2013**,** and is based on data from two Phase III studies demonstrating ZUBSOLV as a an effective treatment for opioid dependence with a solid safety profile. Induction is the initial process a physician performs when a patient is transitioned from the opioid he or she is dependent on to Zubsolv for long term maintenance treatment of opioid dependence.

"The FDA approval for induction treatment constitutes yet another important milestone for ZUBSOLV and enables our field force to promote use of ZUBSOLV from the first day of the patients' treatment for opioid dependence," said Nikolaj Sørensen, CEO and President, Orexo AB. "The addition of the new induction indication can further fuel the positive momentum in Zubsolv sales, where we last month saw an increase in market share with 0.2 percentage point from June, reaching 6.1 percent, the highest level since launch. This is the eighth consecutive week with increasing market share on a four week basis since mid-June".

"The induction indication, along with the coordinated launch of 2.9 mg and 11.4 mg strengths later this year, further differentiates and strengthens the competitive position of ZUBSOLV giving physicians and opioid dependent patients the flexibility to optimize treatment from induction through stabilization, maintenance and tapering phases", said Robert DeLuca, President, Orexo US, Inc.

The approval of the expanded indication for ZUBSOLV was supported by combined data from the Induction, STabilization, Adherence and Retention Trial (ISTART) (Study OX219-006) and Study OX219-007 which showed excellent results with over 90 percent of patients treated with ZUBSOLV remaining on treatment at Day 3 and using a formulation with a 30 percent lower dose of buprenorphine. No significant differences were observed between the safety profiles of ZUBSOLV and generic buprenorphine—the most common treatment-related adverse events (≥5%) during the induction phase were nausea (Zubsolv – 3.5%; generic buprenorphine – 5.3%) and headache (Zubsolv – 5.2%; generic buprenorphine – 5.5%).

"This regulatory milestone supports ZUBSOLV as an effective induction treatment for patients taking their first step on the pathway to recovery from opioid dependence," said Michael Sumner, Chief Medical Officer, Orexo. "We know more than 40 percent of DATA 2000 waivered physicians who are less active treating patients cite initiation of treatment as the greatest challenge. With the induction indication, Orexo can take an active role to 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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Teleconference
Nikolaj Sørensen, CEO, and Michael Sumner, Chief Medical Officer, will also take questions to the induction label and the business in general at a teleconference tomorrow, Wednesday, August 12 at 1:00pm CET.
Dial-in details will be made available on the website, www.orexo.com.

About the Induction, STabilization, Adherence and Retention Trial (ISTART) (Study OX219-006)
The ISTART Trial (n=758) was a randomized, non-inferiority, multicenter study to assess early treatment efficacy when switching between treatments of ZUBSOLV in comparison to generic buprenorphine monotherapy for induction and Suboxone® Film of opioid maintenance therapy. The primary endpoints were retention in treatment at Day 15 and Day 3. On Days 1 and 2, patients received a blinded, fixed dose of ZUBSOLV (5.7/1.4 mg and 5.7/1.4 or 11.4/2.8 mg, respectively) or generic buprenorphine monotherapy (8 mg and 8 or 16 mg, respectively). On Day 3, the patients on generic buprenorphine were switched to Suboxone Film and patients in the ZUBSOLV arm continued to receive ZUBSOLV. Stabilization doses were titrated to a maximum daily dose of 17.1/4.2 mg and 24/6 mg for ZUBSOLV and Suboxone, respectively, based upon clinical symptoms.

Results of the study showed no differences in retention at Day 3 in the per-protocol [ZUBSOLV arm: 93.3% (309/329); generic buprenorphine arm: 92.6% (302/326); p=0.512] or full analysis set [ZUBSOLV arm: 93.2% (357/383); generic buprenorphine arm: 91.7% (344/375); p=0.440]. Clinically and statistically significant improvements were observed in Clinical Opiate Withdrawal Scale (COWS), Subjective Opiate Withdrawal Scale (SOWS), and opioid cravings VAS (Visual Analogue Scale) total scores.

About Study OX219-007
Study OX219-007 (n=310) was a prospective, randomized, multicenter, blinded, parallel-group, active-controlled study comparing advanced formulation ZUBSOLV compared to generic buprenorphine monotherapy for induction of opioid maintenance therapy.

The primary endpoint was retention in treatment at Day 3. On Days 1 and 2, patients received a blinded, fixed dose of ZUBSOLV (5.7/1.4 mg and 5.7/1.4 or 11.4/2.8 mg, respectively) or buprenorphine (8 mg and 8 or 16 mg, respectively). On Day 3, all patients received open-label ZUBSOLV (5.7/1.4 or 11.4/2.8 mg).

Results of the study showed 91.8 percent (235/256) of patients were retained at Day 3 [generic buprenorphine group: 95.3% (122/128); ZUBSOLV group: 88.3% (113/128); p=0.040]. Clinically and statistically significant improvements were observed in COWS, SOWS, and Craving VAS scores for patients in both randomized groups. In addition, improvements in these scores during the blinded phase demonstrated no clinical difference between products.

About Orexo AB
Orexo is a specialty pharmaceutical company commercializing its proprietary product ZUBSOLV® for maintenance treatment of opioid dependence in the U.S. ZUBSOLV is an advanced formulation of buprenorphine and naloxone using Orexo's unique knowledge and expertise in sublingual drug delivery. R&D is focusing on reformulation of known substances to new improved products that meet great unmet medical needs by using its patented proprietary technologies. Orexo's share is listed on Nasdaq Stockholm Exchange Mid Cap (STO: ORX) and is available as ADRs on OTCQX (ORXOY) in the US. Orexo's global headquarters and R&D are based in Uppsala, Sweden.
www.orexo.com

About Orexo US, Inc.
Orexo US, Inc. is an emerging specialty pharmaceutical company marketing improved treatments for opioid dependence using proprietary drug delivery technology. To receive more information please contact Orexo at 1-855-ZUBSOLV.
www.orexo-us.com

For information about opioid dependence, please visit www.outthemonster.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 08:30am CET on August 11, 2015.