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Press release

ZUBSOLV® Market Access Update on Agreement with CVS Caremark and Announcement of New Exclusive Agreement in Managed Medicaid

Uppsala, Sweden– August 4, 2015 - Orexo AB announced today changes to ZUBSOLV® (buprenorphine/naloxone CIII sublingual tablet) managed care formulary **POSITION** for patients suffering from opioid dependence.

Today the PBM, CVS Caremark published their 2016 Standard Formulary List of Excluded Drugs for their commercial clients. Effective from January 1, 2016 Zubsolv has been removed from the preferred position and excluded from the high controlled commercial plans where ZUBSOLV has been the only branded alternative since January 2014. Based on Orexo's experience with CVS Caremark during the past 18 months the high controlled plans impact a minority portion of the overall opioid dependency market within the account. At this time Orexo estimates the direct impact today would effect approximately 10-15 percent of Zubsolv gross sales (0.6 - 0.8 share points). Since January 2014 while Zubsolv has been the exclusive branded alternative, the main branded competitor who had the incumbent position maintained a higher than expected market share of CVS Caremark commercial business, showing the opportunity to maintain market share, while being excluded from the highly controlled plans. During this 18 month period patients and physicians have had a choice to select the generic alternatives and have chosen and been loyal to Zubsolv as their preferred brand, providing Orexo with a good platform to maintain market share.

Orexo continues to progress the discussions with multiple payers in both public and private segments and have signed a multi-year exclusive agreement with a PBM in Managed Medicaid, with the potential to exceed the market share loss that may develop due to the 2016 change in CVS Caremark commercial plans. As previously communicated, Managed Medicaid plans provide a strategic opportunity for ZUBSOLV however the rebates in this managed public segment are typically higher than in the privately insured plans.

For all PBMs, both in commercial and Managed Medicaid, the impact of an agreement and change in formulary position is dependent on the implementation by their insurance clients and both timing and impact on sales is associated with significant uncertainties.

"The news and decision from CVS Caremark to exclude Zubsolv from their highly controlled plans came as a surprise to Orexo, we have continued to gain market share and have benefited from the collaboration since January 2014. Although this decision is disappointing, we are pleased to see market share gains across all

payers during July taking Zubsolv to new all-time-high levels and to announce a new agreement has been signed in Managed Medicaid which is likely to more than compensate for the loss from CVS Caremark commercial business in terms of market share," said Nikolaj Sørensen, CEO and President, Orexo AB.

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About Orexo AB
Orexo is a specialty pharmaceutical company commercializing its proprietary product Zubsolv® for maintenance treatment of opioid dependence in the United States. 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

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**.**
www.zubsolv.com