

**Press release**

## **Zubsolv® gains preferred position on CVS Caremark 2018 formulary**

**Uppsala, Sweden – August 2, 2017** - Orexo AB announced today changes to Zubsolv (buprenorphine and naloxone) sublingual tablet (CIII) managed care formulary position with CVS Caremark for patients suffering from opioid dependence. Zubsolv's position has changed from excluded from reimbursement to reimbursed as a preferred product.

CVS Caremark, one of the largest PBMs in the United States, published their 2018 Exclusion Template Formulary List of Covered Drugs for their commercial clients. Effective January 1, 2018, Zubsolv will be placed in a preferred parity position with the market-leading branded product and the generic will remain in the generic tier. This formulary position places Zubsolv on the national managed care formulary for all exclusion template commercial clients which is the largest portion of CVS Caremark's commercial membership providing pharmaceutical benefits for over 25 million patients. Further, this change in formulary for 2018 means that Zubsolv increased its unrestricted access to over 90 percent of all commercial managed care lives in the United States.

While Zubsolv had been excluded from the CVS Caremark formulary effective January 2016, the loss of market share from CVS Caremark prescriptions has been around 0.8 share points nationally. With the regained preferred status Orexo will be able to compete in a preferred parity formulary position with another brand. Many patients and physicians following the CVS Caremark formulary change have during the last two years remained loyal to Zubsolv maintaining the product as their brand of choice. This patient retention and physician commitment provides Orexo with a platform to recover some of the lost market share. The previous agreement (until December 2015) had Zubsolv as the exclusive branded product on the CVS Caremark exclusion template formulary. The new agreement places Zubsolv in a co-preferred parity formulary position with another brand, which limits the immediate positive impact on market share as there will be no forced switching to Zubsolv.

"I am very pleased with this positive news and the decision by CVS Caremark to again include Zubsolv as a co-preferred product. We have maintained a strong confidence that we would regain the lost preferred position and through significant efforts from our US commercial organization we have succeeded. To be able to compete in the US market, market access is the cornerstone of our commercial strategy in helping patients in the growing opioid epidemic. The inclusion of Zubsolv on the CVS Caremark formulary is a significant step forward to secure Zubsolv gains universal coverage for all patients with commercial insurance and continued profitable growth for Orexo." said Nikolaj Sørensen, CEO and President Orexo AB.

Orexo has a policy of communicating changes in managed care coverage in the Interim Reports. Due to the significant effect on Orexo's share price when the announcement was made to exclude

Zubsolv® from the CVS Caremark managed care formulary effective January 1 2016, the company has made a decision to make an exception from this policy regarding the announcement of above.

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**About ZUBSOLV**

ZUBSOLV (buprenorphine and naloxone) sublingual tablet (CIII) is a prescription medication used to treat adults who are addicted to opioid drugs (either prescription or illegal) as part of a complete treatment program that also includes counseling and behavioral therapy. Treatment should be initiated under the direction of healthcare providers qualified under the Drug Addiction Treatment Act.

**Important safety information**

Do not take ZUBSOLV if you are allergic to buprenorphine or naloxone as serious negative side effects, including anaphylactic shock, have been reported.

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.

ZUBSOLV contains buprenorphine, an opioid that can cause physical dependence with chronic use. Physical dependence is not the same as addiction. Your doctor can tell you more about the difference between physical dependence and addiction. 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.

Your doctor may monitor liver function before and during treatment with ZUBSOLV.

ZUBSOLV is not recommended for initiation of treatment in patients with moderate hepatic impairment due to the increased risk of precipitated withdrawal. However, ZUBSOLV may be used with caution for maintenance treatment in patients with moderate hepatic impairment who have initiated treatment on a buprenorphine product without naloxone.

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.

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. Opioid use may cause adrenal insufficiency, a potentially life-threatening condition. Seek immediate medical attention if you experience nausea, vomiting, anorexia, fatigue, weakness, dizziness, or low blood pressure as these are signs and symptoms that may be associated with adrenal insufficiency.

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 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.

Cases of serotonin syndrome, a rare but potentially life-threatening condition, have been reported when opioids are used along with serotonergic drugs (such as medications used to treat depression and migraines). Be sure to inform your doctor if you are taking or plan to take any serotonergic medications while taking ZUBSOLV.

Before taking ZUBSOLV, tell your doctor if you are pregnant or plan to become pregnant. If you take ZUBSOLV while pregnant, your baby may have signs of withdrawal at birth and that withdrawal is treatable. 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. Nursing mothers: Caution should be exercised when buprenorphine-containing products are administered to a nursing woman. Talk to your doctor about the best way to feed your baby. If you take ZUBSOLV, monitor your baby for drowsiness and difficulty breathing.

Chronic use of opioids may cause reduced fertility. It is not known whether these effects on fertility are reversible.

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.



**This is not a complete list of negative side effects associated with ZUBSOLV®. For a complete list please see full Prescribing Information.**

**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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

For more information about ZUBSOLV (buprenorphine and naloxone) Sublingual Tablet (CIII), please see the respective **full Prescribing Information** and **Medication Guide** at [www.zubsolv.com](http://www.zubsolv.com).

#### **About Orexo**

Orexo develops improved pharmaceuticals based on innovative drug delivery technologies. The focus is primarily on opioid dependence and pain but the aim is to address therapeutic areas where our competence and technologies can create value. The main market today is the US market for the treatment of opioid dependence where the product Zubsolv is commercialized by Orexo. Other products are commercialized by license partners, including Zubsolv in markets outside of the US. Total net sales for 2016 amounted to SEK 705.9 million and the number of employees was 102. Orexo is listed on the Nasdaq Stockholm Mid Cap (ORX) index and is available as ADRs on OTCQX (ORXOY) in the US. The head office, where also research and development is performed, is located in Uppsala, Sweden.

For more information about Orexo please visit, [www.orexo.com](http://www.orexo.com). You can also follow Orexo on Twitter, @orexoabpubl, LinkedIn and YouTube.

#### **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](http://www.orexo-us.com)