Press release

Orexo discloses more information about the improved market access position for Zubsolv® US in 2018

Uppsala, Sweden – December 12, 2017 - Orexo AB today announces specific information about the improved market access position for Zubsolv (buprenorphine and naloxone) sublingual tablet (CIII) in the US effective January 1, 2018, and previously announced in the Interim Report for the third quarter of 2017. Recently the Formulary List of Covered Drugs for 2018 has been announced by all managed care programs, thus enabling Orexo to share more details about the 2018 formulary position for Zubsolv.

Entering 2018, Zubsolv will have stronger market access position than ever in the US. In the commercial segment Zubsolv's formulary access as from January 1, 2018 will be the best of any buprenorphine/naloxone products, branded or generic, with 96 percent coverage. In the fast growing public segment Zubsolv will have significant improvement in access compared to 2017 moving from 28 to 43 percent coverage (as of July 1, 2018). This progress can mainly be explained by Zubsolv´s preferred position at CVS Caremark formulary (also communicated in a press release, August 2, 2017) and by exclusive multi-year contracts with Humana Medicare Part D, Humana Commercial and Envision Rx Commercial.

The Humana Medicare Part D agreement is of high value importance to Orexo as it is the first exclusive contract within the fast growing Medicare Part D segment. Furthermore, Envision Rx, a high control PBM, will also place Zubsolv as the exclusive preferred product on their 2018 Exclusion Template Formulary List of Covered Drugs for their commercial clients. Today, these new exclusive wins combined equate to over 3 percent of the total market for buprenorphine/naloxone products. These exclusive contracts are associated with significant rebates and the impact on Orexo´s sales depends on the market share Zubsolv can obtain within each contract and the potential change in the utilization within each managed care program.

Additionally, Ohio FFS Medicaid program has announced Zubsolv will be a preferred product in parity with one other branded product, while all generics and the third branded alternative will be non-preferred on the states preferred drug list. Today, Ohio FFS Medicaid represents a small portion of the buprenorphine/naloxone prescriptions in Ohio's Medicaid program. However, from July 1, 2018 Ohio FFS Medicaid program will direct all state Medicaid plans and provide Zubsolv access as preferred product to nearly 9 percent of the total public market which equals more than 4 percent of the total market. Today generics are market leaders in the Ohio state Medicaid plans and a significant portion of the market share gains of the generics in 2017 are from these Medicaid plans.

"I am proud to share more details about the material improvements awaiting Zubsolv® at the beginning of 2018. We have learned that market access is critical to gaining market share and an important route to ensure that more patients gain affordable access to Zubsolv. With the opioid crisis in the US escalating it is vital we can offer the managed care providers a cost effective alternative, enabling them to finance treatment for more patients suffering from opioid dependence," says Nikolaj Sørensen, CEO and President Orexo AB.

An interview with Robert DeLuca, President of Orexo US Inc, where he comments on latest developments for Zubsolv and the opioid crisis in the US is also available on our website, www.orexo.com.

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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 ww.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**.

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**. 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**

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