Press release

FDA Approves Unique Low Dosage of Zubsolv®

Uppsala, Sweden – October 6, 2016 – Orexo AB (publ.) announced today that it has received approval from the US Food and Drug Administration (FDA) of a new unique low dose, 0.7mg/ 0.18 mg, tablet of Zubsolv (buprenorphine/naloxone) sublingual tablet (CIII) for the treatment of opioid dependence. The new dosage is expected to be available in US pharmacies in early 2017.

This new introduction extends Orexo's best-in-class offering of the broadest dosage ranges of any buprenorphine/naloxone product on the US market to six individual dosage strengths. By offering the broadest dosage range, Zubsolv enables physicians and patients the most optimal dosing flexibility without compromising the child safety packaging and stability of the product. All Zubsolv dosages are formulated with the advanced, proprietary sublingual tablet formulation providing high bioavailability, a fast dissolve time, small tablet size, and menthol flavor.

The new Zubsolv 0.7mg uniquely provides a fifty percent lower dose than any other buprenorphine/naloxone product approved in the US. Prior to Orexo's development of the 0.7mg dose of Zubsolv, patients requiring a lower dosage than available, resorted to dividing existing buprenorphine/naloxone products into smaller pieces. This practice jeopardizes dosing accuracy, compromises the child-resistant packaging and also exposes the products to humidity which carries the risk of altering the drug's properties. None of the buprenorphine/naloxone products approved in the US today are FDA-approved to be divided into smaller doses.

"The approval of the 0.7mg Zubsolv is another significant milestone for Orexo because it marks the completion of our pharmaceutical development plan for Zubsolv. The new dosage has been developed in response to physician requests to be able to tailor dosing as they taper patients and ultimately provide a lower minimally effective maintenance dose. At Orexo, we are dedicated to improve the treatment of opioid dependence and as part of our commitment, we once again invest in the development of a product explicitly requested by many physicians," said Nikolaj Sørensen, CEO and President of Orexo AB.

The advanced formulation provided by Zubsolv is specifically designed to meet the needs expressed by physicians and patients. Meeting patient needs may have the potential to improve patient adherence, reduce relapse rates and improve patient outcomes. Zubsolv is the only opioid dependence treatment option available in the highest level of child-resistant, unit dose, F1 packaging which is designed to reduce the chance of unintended pediatric exposure.

For further information, please contact:

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About Orexo

Orexo is a specialty pharmaceutical company commercializing its proprietary product Zubsolv® for treatment of opioid dependence in the US. 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.

For more information about Orexo, please visit **www.orexo.com** or follow us on **Twitter** or **LinkedIn**. For further information about Zubsolv in the US, please visit **www.zubsolv.com**.