



Press release

Zubsolv® now launched in the EU, which triggers a EUR 3m milestone payment to Orexo

Uppsala, Sweden – June 18, 2018 - Orexo AB today announces that its partner Mundipharma has initiated the launch of Zubsolv (buprenorphine and naloxone sublingual tablet), for use in the treatment of opioid dependence, in the EU. The launch is triggering a milestone payment of EUR 3 million (approx. SEK 30.6 million) from Mundipharma.

It is estimated that there are approximately 1.3 million high-risk opioid users in Europe.¹ Although estimates vary significantly, the vast majority of high-risk opioid users use heroin.²

“Taking the step out in Europe, is yet another important milestone for Orexo. There is a need for new and innovative treatments in light of such a serious health problem. Zubsolv will be an affordable and user-friendly treatment and the first therapy in Europe with a choice of up to six different strengths. This allows for finer titration and individualized dosing with potential for fewer tablets compared with existing treatments,” says Nikolaj Sørensen, President and CEO, Orexo AB.

For further information, please contact:

Orexo AB (publ.)

Nikolaj Sørensen, President and CEO

Tel: +46 (0)18 780 88 00

email: ir@orexo.com

Henrik Juuel, EVP and CFO

Tel: +46 (0)18 780 88 00

email: ir@orexo.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 products are commercialized by Orexo in the US or via selected partners worldwide. The main market today is the American market for buprenorphine/naloxone products, where Orexo sells the product Zubsolv®. Total net sales for 2017 amounted to SEK 643.7 million and the number of employees at year-end was 90. Orexo is listed on the Nasdaq Stockholm Mid Cap (ORX) and is available as ADRs on OTCQX (ORXOY) in the US. The head office, where research and development is also performed, is situated in Uppsala, Sweden.

¹ European Monitoring Centre for Drugs and Drug Addiction (2017), *European Drug Report 2017*. Available online via: <http://www.emcdda.europa.eu/system/files/publications/4541/TDAT17001ENN.pdf>

² European Monitoring Centre for Drugs and Drug Addiction (2017), *European Drug Report 2017*. Available online via: <http://www.emcdda.europa.eu/system/files/publications/4541/TDAT17001ENN.pdf>



For more information about Orexo please visit, www.orexo.com. You can also follow Orexo on Twitter, @orexoabpubl, LinkedIn and YouTube. For more information about Zubsolv® in the US, see the product and market websites www.zubsolv.com and www.rise-us.com.

About Zubsolv

Zubsolv (buprenorphine and naloxone sublingual tablet) is licensed in the US and EU for the treatment of opioid dependence and used as part of a comprehensive treatment plan, which includes counseling and psychosocial support. EU marketing authorisation was received in Q4 2017 following the submission to the EMA of a registrational bioequivalence study compared to reference product Suboxone® (buprenorphine and naloxone).

Zubsolv has a safety profile that is similar to other buprenorphine and naloxone treatments. The most commonly reported adverse events with Zubsolv include insomnia, headache, constipation, nausea, excessive sweating and drug withdrawal syndrome.

This information is information that Orexo AB (publ.) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 8.00 am CET on June 18, 2018.