Press release

Zubsolv® receives authorization for treatment of opioid dependence in Europe

Uppsala, Sweden – November 20, 2017 – Orexo AB (publ.) today announce that the European Medicines Agency (EMA) has granted a Marketing Authorization (MA) for Zubsolv (buprenorphine and naloxone), a novel rapidly-disintegrating treatment option[i] for opioid dependence.

Zubsolv, is a sublingual tablet licensed for people with opioid dependence within a framework of medical, social and psychological treatment.[ii] It is the first such therapy to be approved in a choice of six different strengths in Europe. This offers the potential for finer titration and individualized dosing with potentially fewer tablets compared with existing opioid dependence medicines. Opioid use disorder is a chronic, relapsing-remitting condition that places a large burden on the individual and society.[iii] With an estimated 1.3 million high-risk opioid users in 2016[iv], opioid dependence is a serious health concern in Europe where heroin accounts for a majority of the illicit opioid misuse.

Nikolaj Sørensen, President and CEO at Orexo AB, said: "Our ambition is to make Zubsolv available to patients outside the US, and this approval is an important step in realizing this goal. We look forward to continuing our journey with Mundipharma, our partner, reaching out with this unique product globally and introducing an important new option in the care of those suffering from opioid dependence."

The approval does not trigger any milestone payment. Next milestone payment is expected when the commercialization of Zubsolv is initiated. Orexo is also entitled to receive further milestone payments as well as tiered royalties on future net sales.

For further information, please contact:

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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.

About Zubsolv

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

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**.

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[i] Webster L et al (2016) Efficacy and safety of a sublingual buprenorphine/naloxone rapidly dissolving tablet for the treatment of adults with opioid dependence: A randomized trial, *Journal of Addictive Diseases,* 35(4), pp325-338

[ii] Zubsolv (buprenorphine and naloxone) – Summary of Product Characteristics (SPC)

[iii] Degenhardt L, et al (2014) The global epidemiology and burden of opioid dependence: results from the global burden of disease 2010 study, *Addiction* (109), pp1320-1333

[iv] European World Drug Report 2017