Press release

CHMP positive opinion for opioid dependence treatment with Zubsolv® (buprenorphine and naloxone) in Europe

- First regulatory milestone for Mundipharma/Orexo partnership in Europe

Cambridge, UK, and Uppsala, Sweden – September 15, 2017 – Mundipharma and Orexo AB (publ.) today announce that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion for Zubsolv (buprenorphine and naloxone sublingual tablet) for use in the treatment of opioid dependence. The European Commission will now review the CHMP opinion and a final decision is expected in Q4, 2017.

The two companies have worked collaboratively in completing the submission. This was based on data from a bioequivalence study, previous pharmacokinetic studies, and Orexo's extensive clinical program that includes data on more than 1,000 opioid dependent patients.[i]

Opioid use disorder is a chronic, relapsing-remitting condition that places a large burden on the individual and society.[ii] It remains a significant health problem[ii] and it was estimated in 2016 that there were approximately 1.3 million high-risk opioid users in Europe.[iii] Although estimates vary significantly, the vast majority of high-risk opioid users use heroin.[iii]

Rachel Gooch, Head of Addiction Therapy at Mundipharma International Limited, said: "This positive opinion is an important step for our collaboration with Orexo, and we are committed to working with them to make this important treatment available to patients in Europe. Opioid dependency is a chronic condition, where new options are very much needed, particularly if they can deter misuse. We very much look forward to being able to support the clinical community and their patients in this underserved area of medicine by offering an alternative treatment option."

Nikolaj Sørensen, President and CEO of Orexo AB, said: "Together with our partner Mundipharma, our ambition is to make Zubsolv available to patients outside the US. The positive CHMP opinion is important progress towards approval to bring Zubsolv to patients suffering from opioid dependence in Europe. I am very pleased with the collaboration with Mundipharma and I look forward to our continuing journey to reach out with this unique product globally. We also share Mundipharma's commitment to addressing unmet patient needs in opioid dependence, and we remain proud they have chosen to commercialise Zubsolv with us."

If approved Zubsolv® will be the first fast dissolving tablet available in six different strengths, providing a greater choice of therapies to patients and clinicians managing addiction to opioids, including heroin. The Zubsolv formulation has been designed to deter misuse, which it is hoped will give people living with heroin addiction the best possible chance to overcome their challenges.

Under the terms of a 2016 agreement with Mundipharma, Orexo will receive a milestone payment pending achievement of an EU marketing authorization and commercialisation of Zubsolv. Orexo are also entitled to receive further milestone payments as well as tiered royalties on future net sales.

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About the Mundipharma network

The Mundipharma global network of privately-owned independent associated companies was founded in 1956 by doctors, and now operates in over 120 countries worldwide. We are focused on developing business partnerships to identify and accelerate meaningful technology across an increasingly diverse portfolio of therapy areas including respiratory, oncology, pain, and biosimilars. Consistent with our entrepreneurial heritage, we like to think we see what others don't by challenging conventional wisdom and asking different and challenging questions. By working in partnership with all our stakeholders, the Mundipharma network develops medicines that create value for patients, payers and wider healthcare systems.

For more information please visit: www.mundipharma.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 please visit: www.orexo.com

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).

References:

[i] Orexo Data on File
[ii] 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
[iii] 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

This information is information that Orexo AB (publ.) is obliged to make public in accordance with the Securities Market Act. The information was submitted for publication, through the agency of the contact person set out above, at 13.45 am CET on September 15, 2017.