Press release

Mundipharma and Orexo AB announce EU regulatory submission for Zubsolv®

- Mundipharma and Orexo make first EU regulatory submission for Zubsolv® (buprenorphine and naloxone sublingual tablet)
- Zubsolv was approved in the US in 2013 for the maintenance treatment of opioid dependence, as part of a complete treatment plan
- Opioid dependence represents a significant public health problem; across Europe there are an estimated 1.3 million high-risk opioid users[1]

Cambridge, UK and Uppsala, Sweden– 4 October, 2016 - Mundipharma and Orexo AB (publ.) have announced the submission of a regulatory submission of a Marketing Authorisation Application (MAA) for Zubsolv (buprenorphine and naloxone) sublingual tablet to the European Medicines Agency (EMA), seeking approval for the treatment of opioid dependence. If approval is received, the buprenorphine and naloxone sublingual tablet would be the first fast dissolving buprenorphine and naloxone product available in six unique strengths for the treatment of opioid dependence in Europe.

Mundipharma and Orexo have worked in partnership to complete the submission and the required bio-equivalence study, comparing Zubsolv to Suboxone® European buprenorphine and naloxone tablets. The pre-submission meeting with the Rapporteur agreed that the results of the bioequivalence study along with supporting data from previous pharmacokinetic studies performed and Orexo's extensive clinical program, including data on more than 1,000 opioid dependent patients, were suitable to move forward with the regulatory filing[2]. In addition, Zubsolv has been approved in the US since July 2013[3] and has resulted in more than 37 million tablets prescribed to date[4] and greater than 44,000 patient year's exposure, providing additional reassurance of product efficacy and safety[5].

Similar to previous studies comparing Zubsolv to Suboxone US Tablet and film formulations[6,7,8] the participants in the European study showed strong preference for Zubsolv. When compared with the Suboxone European tablet, Zubsolv was preferred by 77.0 percent (low dose) and 79.4 percent (high dose) of the subjects[9] and the tablet dissolve times were faster for Zubsolv than for Suboxone[10].

The submission will not trigger any new financial milestones. However Mundipharma is compensating Orexo for specific expenses related to the work required to prepare the submission. The next milestones are pending marketing authorisations and commercialisation of Zubsolv. Orexo is also entitled to receive tiered royalties on future net sales.

Rachel Gooch, Head of Addiction Therapy, Mundipharma International Limited, said: "We are pleased to submit Zubsolv to the EMA for marketing authorization and take a further significant step in our collaboration with Orexo. Opioid dependency is a chronic condition that places a disproportionately large burden on individuals and societies across Europe as well as globally.

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We are committed to working to support people living with opioid use disorders to have the best possible chance to work towards positive change."

Nikolaj Sørensen, CEO and President of Orexo AB, said: "With the regulatory filing to EMA of Zubsolv, Orexo has met another major milestone in the efforts to potentially make Zubsolv available for patients world-wide. Opioid dependence is a growing concern globally and with the unique novel product characteristics of Zubsolv such as fast dissolve time, six unique strengths to suit individual patients' needs and strong patient preference, I am certain Zubsolv could be a welcome alternative for European physicians treating opioid dependence. I am very pleased with the first concrete results of the collaboration with Mundipharma and I am looking forward to working with them to make Zubsolv available in many more countries globally."

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About Mundipharma
Mundipharma and its network of independent associated companies are privately owned companies and joint ventures covering the world's pharmaceutical markets. These companies are committed to bringing to patients the benefits of significant new treatment options in the core therapy areas of pain, respiratory, addiction, oncology and inflammatory conditions. Through innovation, design and acquisition, Mundipharma delivers important treatments to meet the most pressing needs of patients, healthcare professionals and health systems worldwide.

For further information please visit: **www.mundipharma.com**

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**

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® ZUBSOLV is a registered trade mark of Orexo AB.
SUBOXONE is a registered trade mark of Indivior UK Limited

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[10] Mundipharma Data on File ADD-10001

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