



Press release

Orexo signs license agreement with Mundipharma, which obtains ex-US global rights to Zubsolv®

Uppsala, Sweden - June 30, 2016 - Orexo AB (publ.) today announced an agreement granting Mundipharma's network of independent associated companies' exclusive global (ex-US) rights to Zubsolv® (buprenorphine and naloxone) sublingual tablet (CIII), for treatment of opioid dependence. Under the terms of the agreement Orexo receives an upfront payment of 7 million euros. Pending marketing authorizations and commercial milestones Orexo is also entitled to receive further milestone payments and up to low double digit royalties on future net sales. Orexo will also be compensated for specific expenses related to the work required to prepare Zubsolv for markets outside the US.

In addition, the launch of Zubsolv outside the US will increase production volumes and over time this could considerably improve Orexo's gross margin.

Zubsolv is licensed in the US for the treatment of opioid dependence and used as part of a comprehensive treatment plan, which includes counselling and psychosocial support. It is expected to be submitted to the EMA (European Medicine Agency) for marketing authorisation pending the completion of a registrational bioequivalence study compared to reference product Suboxone® tablet (buprenorphine and naloxone). Regulatory filings in other ex-US territories are also planned. Around 20 million people outside the US are suffering from opioid dependence.¹ This new partnership builds on the ambition to provide a greater choice of therapies to those patients and the clinicians managing addiction.

Nikolaj Sørensen, CEO and President of Orexo AB, said: "I am very pleased that Zubsolv soon could have a more global reach. Mundipharma has shown a strong commitment to become a leader in the treatment of opioid dependence and I am proud they have selected to commercialize Zubsolv. I am looking forward to a successful partnership with Mundipharma and working together to hopefully make a new treatment option available to also benefit patients outside the US with opioid dependence. Together with the anticipated increase of physicians prescription rights in the US this year and an exciting pipeline with non-disclosed projects this important commercial collaboration with Mundipharma, will further drive business value."

Antony Mattessich, President and CEO, Mundipharma International Limited commented on the partnership. "We're very excited about this new collaboration and the opportunity to realise the potential of Zubsolv to help patients and healthcare professionals manage opioid dependence with a combination product that is designed to deter misuse. We share the hopes and concerns of

¹ World Drug Report 2015 (United Nations Office on Drugs and Crime)



patients and their families battling heroin addiction. Our ambition is to give people the best possible chance to overcome their challenges in this area of high unmet need.”

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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

Orexo AB (publ.) discloses the information provided herein pursuant to the Financial Instruments Trading Act and/or the Securities Markets Act. The information was submitted for publication at 08:00 am CET on June 30, 2016.