Press release

Positive results from human PK study assessing Orexo's new intranasal naloxone formulations for opioid overdose reversal

Uppsala, Sweden – January 7, 2019. Orexo AB (publ), the fully integrated specialty pharmaceutical company addressing opioid addiction and pain, today announces positive results from the human pharmacokinetic (PK) study OX124-001 in 20 healthy volunteers, assessing Orexo's novel naloxone nasal spray formulations intended for opioid overdose reversal.

The study was a cross-over, comparative, bioavailability study comparing four development formulations of OX124 to Narcan® Nasal Spray 4mg, the current market-leading naloxone rescue medication in the US. All formulations of OX124 were well tolerated and showed substantially higher plasma concentrations of naloxone, sustained duration of elevated plasma concentrations, and equivalent or superior onset time when compared to Narcan®.

Highly potent synthetic opioids such as fentanyl have become the leading cause of death following drug overdoses in the US, with nearly 30,000 fatalities in 2017. Currently available naloxone-based rescue medications struggle to reverse effects of such opioids. Orexo believes that the present results for OX124 will allow for the development of a proprietary rescue medication capable of reversing any overdose, irrespective of which type of opioid has caused it.

The next step for OX124 is to continue to further optimize the formulation and prepare for a pivotal pharmacokinetic bridging study in consultation with the US Food and Drug Administration, FDA. The positive study results will also enable Orexo to accelerate development of the Company's second differentiated rescue drug candidate, OX125, which contains the active substance nalmefene. Assuming further successful development, Orexo expects to file OX124 and OX125 with FDA in 2021 and 2022, respectively.

The addressable market for OX124 and OX125 is large and growing as demand for easy to use, potent overdose reversal medication increases, not only for emergency staff and first responders, but also opioid dependent patients, and as co-prescription for high-dose opioid pain patients. According to Orexo's own estimates, greater levels of co-prescriptions and expanding access for opioid dependent patients may increase the market size from today's USD 300-500 million to USD 1.5-2 billion.

"OX124 forms part of our important work to tackle the opioid crisis in the US, and I am very encouraged by the positive results generated by our R&D team. We look forward to advancing OX124 and OX125 and remain confident that we will be able to develop a product for opioid overdose reversal, in line with our strategy to expand our US commercial footprint," said Nikolaj Sørensen, President and CEO, Orexo AB.

"We are very pleased with the positive results from the PK study which demonstrate OX124's potential to improve the ability to reverse the effect of the most powerful synthetic opioids. The results also pave the way for Orexo to develop a new technology platform that shows great promise for further product development," added Robert Rönn, VP and Head of R&D.

For further information, please contact

Nikolaj Sørensen, President and CEO
Tel: +46 18 780 88 00
E-mail: ir@orexo.com

Robert Rönn, VP and Head of R&D
Tel: +46 18 780 88 00
E-mail: ir@orexo.com

About OX124

OX124 is based on a novel and unique technology developed to provide a rapidly acting naloxone rescue medication with the aim to provide differentiated profile compared to currently marketed products and other products under development. Naloxone is a full opioid receptor antagonist which reverses the effects of opioid agonists, including the life threatening respiratory depressant effects occurring in an opioid overdose.

About OX124-001

OX124-001 was a randomized, open label study designed to evaluate the bioavailability of nasally administered naloxone formulations in healthy subjects. It was a cross-over study performed in 20 volunteers comparing the bioavailability of Orexo's four novel naloxone formulations to Narcan® nasal spray.

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.

For more information about Orexo please visit, **www.orexo.com**. You can also follow Orexo on Twitter, @orexoabpubl, LinkedIn and YouTube.

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 January 7, 2019.