



Press release

## Promising results from human PK study assessing novel ketorolac formulations for treatment of pain

- ***OX338 demonstrated improved bioavailability and tolerability compared to commercially available reference product***
- ***Further work required to optimise product formulation***

**Uppsala, Sweden – January 29, 2020.** Orexo AB (publ.) today announces promising results from its OX338 pharmacokinetic study, evaluating novel formulations of ketorolac, a non-addictive, non-steroidal anti-inflammatory drug (NSAID) for the treatment of pain.

Orexo's OX338 formulations demonstrated improved bioavailability and tolerability compared to the commercially available reference product. In addition, one of the formulations demonstrated more rapid absorption, which may be beneficial when immediate pain relief is needed. The results, however, also indicated further formulation work is required to ensure optimal product properties before progressing to the next stage of development.

**Nikolaj Sørensen, President and CEO at Orexo AB said:** *“The opioid crisis is a severe problem on a global scale and a key part of the solution lies in the development of non-opioid alternatives to effectively treat pain. At Orexo we are dedicated to being a part of the solution and believe OX338 could play a key role in both the treatment of pain and reducing an over-reliance on analgesic opioid products. I am encouraged by the promising pharmacological results generated by our R&D team and look forward to advancing this drug candidate into the hands of patients where it is needed most.”*

For many opioid dependent patients, opioid dependence started after being prescribed an opioid based treatment for the short-term relief of pain, e.g. after an accident or minor medical or surgical procedures. The addressable market for OX338 is therefore large and growing, particularly as demand for effective alternatives to opioid treatment increases. Ketorolac is a potent NSAID drug with an analgesic effect comparable to many opioids used for short-term pain management, and could therefore provide a much-needed alternative to opioid based treatments.

The next step for OX338 is to further optimize the formulation to ensure full commercial potential and to develop a regulatory strategy to effectively bring the product to market in consultation with the US Food and Drug Administration.



**For further information, please contact**

Orexo AB (publ.)

Nikolaj Sørensen, President and CEO

Tel: +46 (0)18 780 88 00

E-mail: [ir@orexo.com](mailto:ir@orexo.com)

Lena Wange, IR and Communications Manager

Tel: +46 (0)18 780 88 00

E-mail: [ir@orexo.com](mailto:ir@orexo.com)

**About study OX338-001**

OX338-001 was a randomized, open label, cross-over study in 20 healthy volunteers to evaluate the bioavailability of OX338 ketorolac formulations. Pharmacokinetics of five development OX338 ketorolac treatments were compared to a commercially available ketorolac reference product.

**About OX338**

OX338 is a novel tablet formulation of ketorolac developed by Orexo for rapid absorption and onset of effects. Ketorolac is a potent NSAID for short term treatment of moderate to moderately severe pain that requires analgesia at the opioid level. In contrast to opioids ketorolac is not addictive or subject to abuse and may replace and limit the use of opioids for such indications.

**About Orexo**

Orexo develops improved pharmaceuticals and digital therapeutics addressing unmet needs mainly within the growing space of addiction. The products are commercialized by Orexo in the US or via partners worldwide. The main market today is the American market for buprenorphine/naloxone products, where Orexo commercialize its lead product Zubsolv® for treatment of opioid use disorder. Total net sales for 2018 amounted to SEK 783.1 million and the number of employees was 129. 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.

The information was submitted for publication at 8 am CET, on January 29, 2020.