Press release

Orexo submits New Drug Application to FDA for OX124, a high-dose rescue medication for opioid overdose

- **OX124 is based on Orexo´s world-class drug delivery platform amorphOX® and is designed to reverse the effect of the most powerful synthetic opioids, such as fentanyl**
- **Synthetic opioids are behind 91 percent of all fatal opioid overdoses in the US[1]**
- **If approved, US launch is expected to be initiated late in H2 2024 or early 2025**

Uppsala, Sweden – September 18, 2023 – Orexo AB (publ.), (STO:ORX) (OTCQX:ORXOY), today announces the submission of the New Drug Application (NDA) to the US Food and Drug Administration (FDA) for OX124, a high-dose rescue medication for opioid overdose with nasal delivery. OX124, is based on Orexo´s world-class drug delivery platform amorphOX® and is designed to reverse the effects of the most powerful synthetic opioids, such as fentanyl.

The submission is supported by data from the pivotal study in healthy volunteers, OX124-002, where OX124 showed a significantly faster and higher absorption of naloxone compared to intramuscular dosing with an injection reference product. In addition, development formulations of OX124 have in a previous exploratory clinical study (OX124-001) in healthy volunteers, demonstrated a more rapid absorption and higher bioavailability compared with the market leading naloxone rescue medication, even with the same dose as the comparator. OX124 is protected by patents until 2039.

If approved OX124 will meet the significant and growing need of more powerful rescue medications improving the possibility to revive individuals who have got an overdose caused by use of synthetic opioids, such as fentanyl. During the latest 12-month period, ending April 2023, the predicted annual number of fatal overdoses in the US counted for more than 110.000.[2] The great majority, 76 percent, refers to opioid overdoses, and of these 91 percent involved synthetic opioids.[3]

The technical issues with the packaging process, which earlier this year gave rise to FDA's request for filing a new NDA, have now been solved in partnership with the contract manufacturer. To ensure the manufacturing process meets the highest reliability requirements, tests, and qualifications have successfully been conducted at the contract manufacturers site.

---

[1] Center of Disease Control and Prevention
[2] Center of Disease Control and Prevention
[3] Center of Disease Control and Prevention

Nikolaj Sørensen, President and CEO of Orexo AB, said: "*Thanks to an excellent team effort, our supply chain for OX124 now meets the highest reliability standards, and we can timely submit a new NDA to the FDA. With the submission of OX124 we are making good progress in expanding our commercial product portfolio in the US and this high-dose life-saving medication has the potential to curb the huge upturn in lethal overdoses seen over the past years and which is grounded in the wide spread of fentanyl. Me and my team look forward to giving broad access to this important and differentiated medication.*"

FDA´s review process is expected to take ten to thirteen months. Orexo is planning to initiate the US launch late in H2 2024 or early 2025.

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**

Lena Wange, IR & Communications Director
Tel: +46 (0)18 780 88 00
E-mail: **ir@orexo.com**

About Orexo
Orexo is a Swedish pharmaceutical company with over 25 years of experience developing improved pharmaceuticals based on proprietary formulation technologies that meet large medical needs. On the US market, Orexo provides innovative treatment solutions for patients suffering from opioid use disorder and adjacent diseases. Products targeting other therapeutic areas are developed and commercialized worldwide with leading partners. Total net sales in 2022 amounted to SEK 624 million, and the number of employees to 126. Orexo is listed on Nasdaq Stockholm's main list and is available as an ADR on OTCQX (ORXOY) in the US.

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

The information was submitted for publication at 8.00 CET on September 18, 2023.