Press release

Orexo announces FDA acceptance of New Drug Application filing 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 effects of the most powerful synthetic opioids, such as fentanyl**
- **Synthetic opioids are behind 91 percent of all fatal opioid overdoses in the US**[1]
- **Prescription Drug User Fee Act date (PDUFA) set to July 15, 2024. If approved, US launch is expected to be initiated late 2024.**

Uppsala, Sweden – November 28, 2023 – Orexo AB (publ.), (STO:ORX) (OTCQX:ORXOY), today announces the New Drug Application (NDA) for OX124 has been accepted for review by the US Food and Drug Administration (FDA). OX124 is a nasal rescue medication for opioid overdose containing a high dose of naloxone and is the first product based on Orexo´s world-class drug delivery platform, amorphOX®. The PDUFA date is set to July 15, 2024, but recent review processes in the category indicate a risk of some delay.

OX124 will meet the growing need for more powerful medications to improve the possibility of reviving individuals experiencing an overdose caused by use of synthetic opioids, such as fentanyl, which today cause 91 percent of all fatal opioid overdoses.[2] OX124 is a potent medication and, in combination with rapid absorption and high bioavailability, this makes it capable of reversing an overdose or sustaining consciousness in a patient who has taken synthetic opioids. AmorphOX is an innovative powder-based technology that, in addition to rapid absorption and high bioavailability, improves stability and reduces sensitivity related to temperature changes. For users and lay-people[3] OX124 has the potential to become an efficient and reliable rescue medication independent of temperature variations during storage, for example its efficacy is not affected at freezing temperatures. OX124 is protected by patents until 2039.

Driven by the need to increase access to overdose medication, low-dose products, including the market leader, have recently been approved by the FDA as non-prescription over-the-counter (OTC) products. Historically, OTC products in the US have had limited reimbursement from insurance companies and, when applying similar industry analogues going forward, this may provide an advantage to high-dose prescription naloxone products, such as OX124. In addition, high-dose prescription products are expected to benefit from the continued expansion of

[1] Center of Disease Control and Prevention

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[3] E.g., police officers, prison personnel, family, and relatives

mandatory co-prescription of naloxone when prescribing opioids to at-risk patients suffering from pain.

Nikolaj Sørensen, President and CEO, said: *"I am pleased the FDA can now start reviewing our rescue drug, OX124. With its high-dose of naloxone and unique formulation, OX124 has the potential to reduce the acceleration in fatal overdoses caused by the widespread misuse of synthetic opioids. We're approaching this launch in a rapidly growing market that's currently undergoing major changes, which are closely monitored by me and my commercialization team in the US. I feel confident we can take advantage of these recent developments to reach many people acutely in need of more powerful overdose rescue medications. With approval, we intend to initiate commercial activities during the second half of 2024 with a focus on obtaining reimbursement ahead of a broader launch into retail pharmacies early in 2025."*

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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 (former Twitter), LinkedIn, and YouTube.

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