Press release

Orexo expects FDA filing of OX124 mid 2022

- **OX124 is designed to reverse the effect of the most powerful synthetic opioids**
- **Synthetic opioids are behind the majority of fatal overdoses in the US, a development expected to increase due to Covid-19**
- **New Drug Application (NDA) filing expected mid 2022**

Uppsala, Sweden – January 29, 2021 – Orexo AB (publ.), **(STO:ORX) (OTCQX:ORXOY)** today announces that it is expecting to file its flagship pharmaceutical pipeline asset OX124 with the US Food and Drug Administration mid-2022. OX124 is expected to follow the FDA's standard submission and review timelines, as the FDA did not grant Fast Track Designation to the product. Given the medical need to swiftly make powerful rescue medications available to those in need, Orexo will continue to work closely with the FDA to expedite the route to approval. The FDA's decision is not related to the product, but is based on an overall assessment whether the development program meets the strict requirements to receive Fast Track Designation.

Based on Orexo's patent-protected nasal delivery technology, OX124 is a powerful naloxone rescue medication, designed to reverse opioid overdoses, including those from synthetic opioids, such as fentanyl.

Highly potent synthetic opioids, such as fentanyl, are the leading cause of death following drug overdoses in the US with over 37,000 fatalities in 2019. As a consequence of the Covid-19 pandemic, 2020 is projected to report another all-time-high of fentanyl-related overdose deaths underlining the need for more powerful and faster-acting rescue medications.

In an exploratory clinical study (OX124-001) in healthy volunteers, OX124 has shown superior onset time, substantially higher plasma concentrations of naloxone and sustained duration of elevated plasma concentrations when compared to the current market leader.

Nikolaj Sørensen, President and CEO of Orexo AB, said: *"I am disappointed by the decision from the FDA and the short delay it causes to our opportunity making this powerful rescue medication, countering the effects of synthetic opioids, available for patients. However, several routes remain to expedite the time to filing and approval and we look forward to working closely with the FDA to make this important life-saving medication available to millions of people in need as swiftly as possible."*

The addressable market for OX124 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

for opioid dependent patients, and as co-prescription for high-dose opioid pain patients. According to Orexo's 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. If approved, OX124 is estimated to have a sales potential of USD 70 –110 million.

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About OX124-001
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®.

About Orexo
Orexo develops improved pharmaceuticals and digital therapies addressing unmet needs within the growing space of substance use disorders and mental health. 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 commercializes its lead product ZUBSOLV® for treatment of opioid use disorder. Total net sales for 2020 amounted to SEK 664 m and the number of employees was 138. Orexo is listed on the Nasdaq Stockholm Mid Cap (ORX) and is available as ADRs on OTCQX (ORXOY) in the US. The company is headquartered in Uppsala, Sweden, where research and development activities are performed.

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

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