Press release

Orexo shares new timeline for the high-dose rescue medication for opioid overdose, OX124

Uppsala, Sweden – **April 3, 2023** – Orexo AB (publ.), **(STO:ORX) (OTCQX:ORXOY)**, today announces the expected US launch of OX124, a high-dose rescue medication for opioid overdose, is delayed to late 2024 from previously first half of 2024, if approved by the US Food and Drug Administration (FDA) according to their ordinary timelines.

The updated timeline follows unexpected technical issues with the equipment used for the secondary packaging process in the outsourced supply chain for OX124 and there is a need for qualification and documentation of the packaging process to meet the reliability requirements. As a result, FDA has requested Orexo to resubmit a New Drug Application (NDA), when Orexo has completed the qualification and can confirm the packaging process is ready for FDA inspection.

The request for a resubmission is solely based on the technical issues in the packaging process and no other concerns have been shared by the FDA. Orexo expects to resubmit the file during Q3 2023 with approval expected second half of 2024

Nikolaj Sørensen, President and CEO of Orexo AB, said: *"As a lifesaving rescue medication OX124 must meet the highest standard of reliability and quality in the manufacturing process. This requires Orexo and our manufacturing partners to scrutinize all aspects of the value chain and any potential issues are assessed in detail before initiating commercial manufacturing. I am disappointed with the delay in the process of bringing this life saving medication to the US market. However, I am pleased the manufacturing team is confident we have a solution to the technical issues in the packaging process and that it has no impact on the chances for final approval. When solved, this will even further strengthen the supply chain for our future rescue medications, such as OX640 and OX125."*

On February 3, 2023, Orexo submitted the NDA with the FDA for OX124. The submission is supported by successful data from the pivotal study in healthy volunteers, OX124-002, and in addition by data from the exploratory clinical study (OX124-001). OX124 is protected by patents until 2039.

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About opioid overdose
Opioid overdose is a life-threatening condition, characterized by loss of consciousness and respiratory depression. Opioid overdoses can be treated with the opioid antagonist naloxone. During the 12-month period ending October 2022, the predicted annual number of fatal opioid overdoses in the US exceeded 81,000[1]. Nine out of ten opioid overdose deaths involved synthetic opioids, including fentanyl. The switch to highly potent synthetic opioids has led to more severe overdoses, prompting the need for high-dose naloxone products.

About OX124-002
This pivotal trial was a 4-period cross-over, comparative bioavailability study in healthy volunteers, comparing two dose regimens of OX124 to two dose regimens of an injection reference product. The study met its primary endpoints with naloxone exposure within the targeted interval. In addition, it showed a significantly faster and higher absorption of naloxone compared to intramuscular dosing with the injection reference product. OX124 was also well tolerated.

About OX124-001
This study was a cross-over, comparative, bioavailability study comparing four development formulations of OX124 to the market leading naloxone rescue medication (4 mg) 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 versus the comparator.

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 2022 amounted to SEK 624 million and the number of employees was 126. Orexo is listed on the Nasdaq Stockholm Main Market (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.

[1] **https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm**. During the same period the predicted annual number of total fatal overdoses amounted to more than 107,000.

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

The information in the press release is information that Orexo is obliged to make public pursuant to the EU Market Abuse Regulation. The information was sent for publication, through the agency of the contact person set out above, on April 3, 2023, at 8 am CET.