Press release

Orexo shares new information on OX124, a high-dose naloxone rescue medication in development for opioid overdose

Uppsala, Sweden – July 16, 2024 – Orexo AB (publ.), (STO:ORX) (OTCQX:ORXOY), today announces that the company has received a complete response letter (CRL) from the US Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for OX124, a high-dose naloxone rescue medication in development for opioid overdose. The NDA was submitted to the FDA on September 18, 2023. The CRL indicates the need for an additional Human Factors (HF) study, which is in line with previous communication. Furthermore, additional technical data on the final commercial product has been requested. The CRL does not indicate a need for additional clinical or non-clinical studies.

In response to the comments received in April 2024, Orexo has worked intensively to optimize the instructions of use. To meet the FDA requirement, a new HF study has been successfully completed. The requirement from FDA to provide additional technical data was unexpected, and Orexo will now work expeditiously in consultation with the FDA to address this to enable a resubmission of the NDA to FDA as soon as possible. The review period following the resubmission of the NDA will be up to six months.

The type of technical data required by FDA has already been generated from our pilot scale manufacturing and the data were included in the NDA. Orexo´s assessment is that the submitted data support approval however, FDA does not agree and has requested data from the established commercial scale manufacturing.

"I am impressed by the vigour and agility of the teams in Sweden and the US in addressing FDA's concerns from April regarding the instructions for use and our ability to complete a new human factors study shortly. However, I am surprised with the agency´s other requests with regards to additional technical data from final commercial product, but I am confident we can address this efficiently" said Nikolaj Sørensen, President and CEO, of Orexo. "We remain confident our powerful life-saving medication, OX124, can contribute to reducing the steep number of Americans who die from overdoses caused by the increasingly prevalent synthetic opioids. Me and my team are determined to continue taking the necessary actions to swiftly provide the FDA with the additional information."

Upon approval OX124 will meet the growing need for more powerful medications and higher doses of naloxone for reversal of opioid overdoses involving synthetic opioids, such as fentanyl or

fentanyl analogues, which today cause 92 percent of all fatal opioid overdoses.[1] OX124 is a high dose proprietary naloxone formulation and, as a result of rapid absorption and high bioavailability, can reverse an overdose or sustaining consciousness in a patient who has taken synthetic opioids.

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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 2023 amounted to SEK 639 million, and the number of employees to 116. 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.

This information is information that Orexo AB (publ.) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 8 pm CET on July 16, 2024.

[1] Center of Disease Control and Prevention, predicted number of fatal overdoses ending Dec. 2023