



Press release

Orexo strengthens IP rights for overdose rescue drug OX124

- **Patent protection until 2039**
- **Previous human pharmacokinetic (PK) study showed significantly better PK profile when compared to market leading product**

Uppsala, Sweden – January 27, 2021 – Orexo AB (publ.), (STO:ORX) (OTCQX:ORXOY) today announces that the company has further strengthened the intellectual property (IP) for its flagship pharmaceutical pipeline asset OX124, a naloxone rescue medication for the treatment of opioid overdose. The US Patent and Trademark Office (USPTO) has issued a new patent protecting the product until 2039.

The new patent, US 10,898,480, is the second US patent for OX124. The first patent, US 10,653,690, was issued by the USPTO in the summer of 2020. At that time, the first patent for Orexo's nalmeferene overdose rescue medicine, OX125, was also issued (US 10,729,687), as previously announced in the Interim Report for Q2, 2020. Both of these patents protect the respective products until 2039.

Based on Orexo's innovative scalable intranasal formulation technology, OX124 is a powerful naloxone rescue medication, designed to reverse opioid overdoses, including those from synthetic opioids, such as fentanyl. In a previous human PK study of OX124 (OX124-001), all formulations of OX124 were found to be well tolerated and showed substantially higher plasma concentrations of naloxone, sustained duration of elevated plasma concentration, and equivalent or superior onset time when compared to the current market leading product.¹

Nikolaj Sørensen, President and CEO, said: *“Recognizing the potential of OX124 early in its development, we have secured strong IP-rights for this novel and scalable intranasal formulation technology. Strong patent protection for this promising asset is critical to ensure the successful commercialization of OX124. Too many people in the US are dying from overdoses caused by synthetic opioids, such as fentanyl. Covid-19 has exacerbated this crisis further, underlining the urgent need for more powerful and faster-acting rescue medications. We believe OX124 could reverse this trend and look forward to reporting further progress on its development over the coming months.”*

OX124 is planned to enter a pivotal bridging study in Q2 2021. A New Drug Application (NDA) is expected to be filed with the US Food and Drug Administration (FDA) in Q1 2022, which is based on

¹ <https://orexo.com/investors/regulatory-press-releases/2019-01-07-positive-results-from-human-pk-study-assessing-orexo-s-new-intranasal-naloxone-formulations-for-opioid-overdose-reversal>



OX124 being granted Fast Track Designation by FDA, which is expected to be received in Q1 2021. Potential net sales for OX124, five years post launch, is in the range of USD 70 – 110 million.

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US market for overdose rescue medications

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.

About 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 commercialize its lead product ZUBSOLV® for treatment of opioid use disorder. Total net sales for 2019 amounted to SEK 844.8 million and the number of employees was 127. Orexo is listed on the Nasdaq Stockholm Mid Cap (ORX) and is available as ADRs on OTCQX (ORXOY) in the US. The head office, where research and development is also performed, is situated in Uppsala, Sweden.

For more information about Orexo please visit, www.orexo.com. You can also follow Orexo on Twitter, [@orexoabpubl](https://twitter.com/orexoabpubl), LinkedIn and YouTube.

The information was submitted for publication at 8 am CET, on January 27, 2021.