Press release

Orexo resubmits NDA for IZIPRY™ to the FDA, a high-dose rescue medication for opioid overdose

- IZIPRY is based on Orexo's world-class AmorphOX® drug delivery platform and is designed to reverse overdoses involving highly potent synthetic opioids such as fentanyl
- The NDA resubmission addresses the items identified in the FDA's Complete Response Letter
- Orexo expects FDA review to commence following acceptance of the resubmission

Uppsala, Sweden – September 29, 2026 – Orexo AB (publ.) **(STO: ORX) (OTCQX: ORXOY)** today announces the resubmission of the New Drug Application (NDA) for IZIPRY (naloxone nasal powder) to the U.S. Food and Drug Administration (FDA) was completed on September 29th 2026.

IZIPRY is a high-dose naloxone rescue medication for opioid overdose based on Orexo's proprietary powder-based drug delivery platform AmorphOX®. The product has been specifically designed to address the growing prevalence of overdoses requiring high doses of naloxone and involving highly potent synthetic opioids such as fentanyl[1]. Real-world evidence shows increasing use of multiple naloxone administrations (MNA) by bystanders and EMS providers [2,3]. The United States Drug Enforcement Agency (DEA) recently advised that fentanyl combined with emerging synthetic opioids might require several doses of naloxone to be effective[4]. Combining a high-dose strength with rapid absorption and high bioavailability, IZIPRY has the potential to reduce repeat dosing and rapidly reverse the life-threatening opioid overdose.

The resubmission includes additional information and documentation addressing the observations communicated by the FDA in its Complete Response Letter (CRL) issued in July 2024. Since receiving the CRL, Orexo has worked closely with manufacturing and development partners to fully address the identified deficiencies and further strengthen the application package.

Nikolaj Sørensen, President and CEO of Orexo AB, said:
"The NDA resubmission for IZIPRY represents an important milestone for Orexo and reflects a tremendous effort by our team and external partners. We believe the application comprehensively addresses the points raised by the FDA and we look forward to continuing the review process. The opioid crisis continues to have devastating consequences across

communities in the U.S., and we remain committed to bringing this innovative rescue medication to patients, caregivers and healthcare professionals in need of effective overdose treatment options."

FDA is expected to notify the company regarding acceptance of the resubmission and communicate an updated review timeline in the coming weeks. Orexo will provide further updates as the regulatory process progresses.

Commercialization and partnership opportunities
Orexo continues preparations for the potential commercialization of IZIPRY in the United States. If approved, IZIPRY is expected to address the growing demand for more powerful rescue medications in a market increasingly affected by synthetic opioids such as fentanyl. The company is also evaluating opportunities to maximize the value of IZIPRY through commercial partnerships ensuring market access and broad patient reach.

About IZIPRY™
IZIPRY is a high-dose naloxone nasal powder rescue medication for opioid overdose. The product is based on Orexo's proprietary AmorphOX® technology, enabling rapid absorption, high bioavailability and improved stability compared with conventional formulations. IZIPRY is designed to address the increasing need for effective overdose rescue medications in the era of synthetic opioids. IZIPRY is under review by the FDA.

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About Orexo
Orexo is a Swedish pharmaceutical company dedicated to advance treatments for severe diseases and life-saving rescue medications to meet future healthcare needs. At the core of our innovation is AmorphOX®, a proprietary drug delivery technology that improves bioavailability and stability for both large and small molecules, enabling new approaches to administration, manufacturing, and distribution. With over 30 years of experience and multiple drugs approved globally, Orexo is advancing a diversified pipeline of programs in clinical and preclinical development. The company collaborates with partners in research, development, and commercialization. Headquartered in Uppsala, Sweden, Orexo is listed on Nasdaq Stockholm's main market and trades as ADRs on the OTCQX market in the United States.

For more information please visit www.orexo.com. You can also follow Orexo on X, LinkedIn, and YouTube.

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References:

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[3] Abdelal R, Banerjee AR, Carlberg-Racich S, Darwaza N, Ito D, Epstein J. The need for multiple naloxone administrations for opioid overdose reversals: A review of the literature. Subst Abus. 2022;43(1):774-784. doi: 10.1080/08897077.2021.2010252. PMID: 35112993.

[4] https://www.dea.gov/press-releases/2026/05/12/public-safety-advisory