

Press release

Orexo develops a nasal adrenaline medication based on the novel amorphOX™ platform

- The development pipeline is broadening with a nasal adrenaline medication, targeting a global and growing unmet medical need
- If approved, the medication would provide important benefits to patients and health care systems ensuring the correct adrenaline dose is both reliably and conveniently available when needed
- Development and commercial partnerships will be considered

Uppsala, Sweden – December 2, 2021 – Orexo AB (publ.), (STO:ORX) (OTCQX:ORXOY) today announces it has initiated a new pharmaceutical development project, OX640, a nasal adrenaline product for the emergency treatment of allergic reactions.

Adrenaline is commonly used for the emergency treatment of allergic reactions, including anaphylaxis, which is a global and growing health problem. The market size today exceed USD 2 billion and is expected to show continuous strong growth in the coming years.¹

The market is currently dominated by the use of auto-injectors for intramuscular or subcutaneous administration of injection solutions of adrenaline, although new delivery alternatives are under development.

Adrenaline is a very unstable active ingredient sensitive to chemical degradation, which is the reason why today's commercial adrenaline products have limited shelf-life with restrictive storage conditions.

OX640 is based on Orexo's proprietary drug delivery platform amorphOX™, and shows promising chemical and physical stability data. In addition to providing allergic patients with a more convenient, needle-free alternative to auto-injectors currently on the market, an adrenaline product that provides greater flexibility in relation to how it can be handled and stored should provide significant benefits to patients and healthcare systems, ensuring the correct adrenaline dose is available when needed.

Nikolaj Sørensen, President and CEO of Orexo AB, said: *"Our recently announced amorphOX™ platform has allowed us to initiate the development of a differentiated nasal adrenaline product with significant commercial potential. Data generated so far indicates we can develop a product with true and meaningful improvements of currently marketed products on a global market. OX640 has the potential to transform the adrenaline market offering nasal delivery and less*

¹ <https://www.biospace.com/article/epinephrine-market-size-to-reach-usd-4-76-billion-in-2028-says-reports-and-data/?keywords=adrenalin+market>



restricted handling and storage requirements. I am looking forward to the continued development of OX640 and to explore potential partnerships in development and commercialization.”

Orexo has consulted with the US Food & Drug Administration on the development of OX640 and on the basis of their feedback outlined a development pathway. Orexo is currently optimizing the OX640 formulation and expects to perform a first explorative human clinical pharmacokinetic study in the second half of 2022. The results of the study are decisive for the final development plan and timeline. Furthermore, Orexo will be able to leverage investments and learnings made from the OX124 and OX125 projects (overdose rescue medications) in the continued development and future commercial manufacturing of OX640.

Orexo will consider the right partnership strategy for the product, but will explore opportunities for development- and commercialization partnerships during 2022.

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About amorphOX™

Orexo's proprietary drug delivery platform, amorphOX™, is a powder made up of particles which are built using a unique combination of a drug, carrier materials and, optionally, other ingredients. The particles are presented as an amorphous composite of the various ingredients providing for excellent chemical and physical stability, as well as rapid dissolution. The technology works for a broad scope of active ingredients and has been validated in several human clinical studies showing rapid and extensive drug exposure.

About Orexo

Orexo develops improved pharmaceuticals and digital therapies addressing unmet needs within the growing space of substance use disorders and mental illness. The products are commercialized by Orexo in the US or via partners worldwide. The main market today is the US market for buprenorphine/naloxone products, where Orexo commercializes its lead product, ZUBSOLV®, for treatment of opioid use disorder. Total net sales for Orexo in 2020 amounted to SEK 664 million 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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