Press release

Orexo's nasal adrenaline rescue medication OX640 enters clinical development

- OX640 has the potential to provide important benefits to patients and healthcare systems ensuring the correct adrenaline dose is both reliably and conveniently available - for the emergency treatment of allergic reactions
- If approved, the product will target a global growing market, today amounting to USD 2 billion
- Development and commercial partnerships are considered

Uppsala, Sweden – July 5, 2022 – Orexo AB (publ.), **(STO:ORX) (OTCQX:ORXOY)** today announces it has successfully initiated the first explorative human clinical study (OX640-001) for OX640, an adrenaline rescue medication with nasal delivery. The study aims to determine the relative bioavailability and absorption characteristics of investigational OX640 formulations versus an intramuscular adrenaline injection in healthy volunteers.

Adrenaline is commonly used for the emergency treatment of allergic reactions, including anaphylaxis. First line treatments today are intramuscular auto-injector products. Since adrenaline is a very sensitive active ingredient that easily undergoes degradation, currently marketed injection products all contain antioxidant chemical additives to help reduce degradation. Despite these additives, and that these products require strictly controlled handling and storage, they still suffer from having limited shelf-life.

Orexo's OX640 product is a nasal adrenaline formulation based on its proprietary drug delivery platform amorphOX®. Stability data generated so far for OX640 strongly indicates the potential for an adrenaline product with significantly improved stability versus today's injection products, both in terms of allowed storage temperatures as well as shelf-life. These encouraging data has been obtained without the addition of any antioxidants.

In addition to offering allergic patients with a product that provides greater flexibility in terms of handling and storage, OX640 provides a less bulky, more convenient and needle-free alternative to auto-injectors.

Robert Rönn, SVP and Head of R&D at Orexo AB, said: *"I am very proud that the team at Orexo has, once again, timely allowed us to reach this important milestone. Our nasal adrenaline formulation has the potential to provide allergic patients with a truly improved and differentiated product and we are looking forward to the study results later this year."*

The prevalence of allergic reactions, including anaphylaxis, is a global and growing health problem. The global market size today exceeds USD 2 billion and is expected to show continuous strong growth in the coming years.[1]

Nikolaj Sørensen, President and CEO at Orexo AB, said: "*In the development of our rescue medication for overdoses, OX124, the aim was to develop a medicine that is not only faster than the existing alternatives, but also more powerful and with longer duration. Solving this equation led to the development of a novel and unique drug delivery platform, amorphOX®, which in exploratory studies has proven to be very scalable as it works with a broad scope of drugs. Our adrenaline project, OX640, is a very promising example capitalizing on this platform and which open new exciting opportunities that go beyond the treatment of mental illness and substance use disorders.*"

Orexo are exploring product development and commercialization partnerships. Costs related to the study are included in the company´s OPEX guidance for 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 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 2021 amounted to SEK 565 million and the

[1] Biospace, June 11, 2021

number of employees was 121. 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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