Press Release

Orexo announces positive data from phase 1 clinical study for OX640 - a nasal epinephrine rescue medication for allergic reactions

- **All four investigational formulations of OX640 were extensively absorbed and rapidly achieved clinically relevant plasma levels of epinephrine**
- **Data available today indicates significantly improved stability compared to current standard of care in a broad range of temperatures**
- **Targeted epinephrine market for auto-injectors exceeds USD 2 billion and expects to show an annual growth of 8-9 percent[1]**
- **Partnership strategies evaluated for continued development and commercialization**

Uppsala, Sweden – October 11, 2022 – Orexo AB (publ.), **(STO:ORX) (OTCQX:ORXOY)** today announces positive results from the first explorative human clinical study (OX640-001) for its nasal epinephrine (adrenaline) rescue medication for allergic reactions, OX640. The study was a comparative bioavailability study performed in 40 healthy volunteers assessing four investigational formulations of OX640 compared to a marketed epinephrine auto-injector.

All four investigational formulations were extensively absorbed and rapidly achieved clinically relevant plasma levels of epinephrine comparable to the reference product. Furthermore, all four OX640 formulations showed concentration dependent effects on heart rate and blood pressure, a pharmacological response relevant for the treatment of allergic reactions. Local and systemic safety findings were generally consistent with known effects of epinephrine and there were no findings that raised any safety concerns.

Robert Rönn, SVP and Head of R&D at Orexo, said: *"The study results are truly exciting, and I am looking forward to the continued development of this important and differentiated product. The data also provides further validation of our drug delivery platform amorphOX® and solidifies Orexo as a leader in advancing drug delivery with amorphous formulations and nasal delivery".*

Epinephrine is commonly used for the treatment of allergic reactions, including anaphylaxis. First line treatments today are intramuscular auto-injector products. The market for these products today exceeds a value of USD 2 billion and is expected to show an annual growth of 8-9 percent.[2] In addition to offering superior stability, in terms of both storage temperature ranges and shelf-life, OX640 provides a less bulky, more convenient, and needle-free alternative to products on the market and under development.

OX640, which is based on Orexos drug delivery platform amorphOX®, has a granted patent in

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

[2] See above

Europe securing exclusivity until 2041 and several other patent applications pending approval across the globe, including the US.

Nikolaj Sørensen, President and CEO of Orexo, said: *"Led by the development of OX124, our rescue medication for opioid overdose, we have continued to develop the amorphOX® platform and we are testing it in a wide range of both small and large molecules. With the positive results from the OX640 study, we once again show proof of concept of the excellent bioavailability provided by this scalable platform. The strong clinical and stability data, the global market need and Orexo's ability to shorten the time to market through our established supply chain, make this product attractive for partners all over the world".*

For pharma products based on the amorphOX® drug delivery platform and that go beyond Orexo's key therapeutic areas within mental illness and substance use disorders, such as OX640, Orexo will seek partnerships for both continued development and commercialization.

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About OX640-001
OX640-001 is a randomised sequence, single-centre, open label, 5-period crossover, phase 1 comparative bioavailability study with the primary objective to determine the relative bioavailability and absorption characteristics of four investigational formulations of OX640 versus an intramuscular auto-injector of epinephrine.

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 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.