PRESS RELEASE
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OREXO INITIATES NEW STUDY OF OX640 IN PARTICIPANTS WITH ALLERGIC RHINITIS

- **OX640 is an intranasal rescue medication for the treatment of severe allergic reactions (incl. anaphylaxis) with powder-based epinephrine**
- **OX640 is based on Orexo´s proprietary drug delivery platform, AmorphOX®, and has demonstrated positive data in a phase 1 clinical study in healthy volunteers**
- **The new study will investigate the performance of OX640 in participants with allergic rhinitis**

Uppsala, Sweden – October 23, 2024 – Orexo AB (publ.), (STO:ORX) (OTCQX:ORXOY), today announces the first participants have been dosed with OX640, an intranasal rescue medication for severe allergic reactions (incl. anaphylaxis) with powder-based epinephrine, in a new study in subjects with allergic rhinitis (hay fever). The study will be completed during 2024 with results available early in 2025.

Following the positive results from the phase 1 clinical study, OX640-001, where OX640 showed absorption of epinephrine and effects on blood pressure and heart rate equivalent to an epinephrine intramuscular auto-injector, Orexo now advances the development of OX640. In the new study, OX640-002, the epinephrine absorption from OX640 will be investigated in participants with and without allergic symptoms in the nose. As patients may experience allergic symptoms in the nose during anaphylaxis, it is critical to understand the absorption of epinephrine from Orexo's unique powder formulation under these conditions.

The study is a cross-over study in 30 participants with allergic rhinitis and involves four treatment periods. In one of the periods, a small dose of an allergen will be sprayed into the nose of the participants to trigger an allergic reaction before being treated with OX640. This will be compared with absorption of epinephrine from OX640 without the allergen, and a commercial intramuscular epinephrine product. The fourth period will be used to document dose proportionality of OX640. In addition to the absorption of epinephrine, effects on blood pressure and heart rate will be measured as relevant parameters to understand the effect of OX640 in case of an anaphylaxis.

Robert Rönn, SVP and Head of R&D, said: *"Anaphylaxis is a serious and life-threatening condition, making it essential to ensure that OX640 remains effective even in the presence of nasal allergic symptoms. The study addresses key development and regulatory requirements and is an important step in advancing the project towards regulatory approval. The performance of OX640 under allergic rhinitis conditions has also been requested in many discussions with health care providers and with potential partners."*

The study is expected to cost SEK 11 million. Most of these costs will be recognized in 2024 and are included in the communicated financial outlook for 2024.

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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 OX640
OX640 is an intranasal rescue medication for the treatment of severe allergic reactions (incl. anaphylaxis) with powder-based epinephrine. The product is based on Orexo´s proprietary drug delivery platform AmorphOX providing rapid and extensive systemic drug absorption after nasal administration as well as excellent physical and chemical stability. Thanks to its unique properties, OX640 has the potential to provide allergic patients with a needle-free, convenient, and rapidly acting allergy rescue product that also has long shelf-life and allows for flexible storage, both in hot and cold temperatures.

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 Orexo
Orexo is a Swedish pharmaceutical company with 30 years of experience developing improved pharmaceuticals based on proprietary formulation technologies that meet large medical needs. On the US market, Orexo provides innovative treatment solutions for patients suffering from opioid use disorder and adjacent diseases. Products targeting other therapeutic areas are developed and commercialized worldwide with leading partners. Total net sales in 2023 amounted to SEK 639 million, and the number of employees to 116. Orexo is listed on Nasdaq Stockholm's main list and is available as an ADR on OTCQX (ORXOY) in the US.

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

Attachments
Orexo initiates new study of OX640 in participants with allergic rhinitis