OREXO ANNOUNCES POSITIVE TOPLINE DATA FROM CLINICAL STUDY OF OX640 IN SUBJECTS WITH AND WITHOUT ALLERGIC RHINITIS

- **OX640 is a nasal rescue medication with powder-based epinephrine for the treatment of allergic reactions (incl. anaphylaxis) and is based on the proprietary AmorphOX® technology**
- **The clinical study, OX640-002, evaluated both pharmacokinetic and pharmacodynamic effects of OX640 in subjects with and without allergic rhinitis**
- **OX640 treatments achieved clinically relevant plasma levels of epinephrine more rapidly than the intramuscular reference product**
- **Absorption from OX640 under allergic rhinitis conditions was significantly faster than under normal conditions, supporting rapid onset of effect also in patients with airway symptoms.**

Uppsala, Sweden – January 10, 2025 – Orexo AB (publ.), (STO:ORX) (OTCQX:ORXOY), today announces positive topline results from the clinical study OX640-002. The study evaluated the performance in subjects with and without allergic rhinitis when treated with Orexo´s nasal rescue medication including powder-based epinephrine, OX640.

The study was a cross-over study in 30 subjects assessing absorption and pharmacodynamic effects of epinephrine from two doses of OX640, with one of the doses also administered during ongoing allergic rhinitis symptoms. Exposure was compared to a commercial intramuscular injection.

Topline data analysis demonstrates that OX640 treatments achieved mean epinephrine plasma levels associated with clinical efficacy more rapidly than the intramuscular injection, with dose-dependent exposure levels. Absorption under allergic rhinitis conditions was significantly faster than under normal conditions, supporting rapid onset of effect also in patients with significant airway symptoms. OX640 formulations typically produced more pronounced increases in blood pressure and heart rate than the intramuscular injection, which are key effects for treatment of anaphylaxis.

Systemic safety was in line with the known pharmacology of epinephrine and local effects were transient and tolerated. There were no severe or serious adverse events.

Robert Rönn, SVP and Head of R&D, said: *"We are pleased with the outcome of the study which further support the utility of our OX640 epinephrine nasal powder for treatment of anaphylaxis, even in case of allergic rhinitis symptoms. Importantly, the study results allow us to decide on the final commercial formulation and dose, which is critical to advance the project towards regulatory approval. The data further reinforces our view that OX640 has the potential to be a unique and differentiated needle-free epinephrine product."*

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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 on Orexo, visit www.orexo.com. Follow Orexo on X, LinkedIn, and YouTube.

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 study OX640-002
The study was a 4-period cross-over study in 30 otherwise healthy subjects with seasonal allergic rhinitis. The study was conducted off allergy season with no ongoing allergy symptoms in subjects. Epinephrine plasma levels, blood pressure and heart rate were collected after administration of two different doses of OX640 and 0.3 mg intramuscular epinephrine. In one treatment period, one of the OX640 doses was administered following nasal administration of allergens, producing acute allergic rhinitis symptoms in the subjects.

The information was submitted for publication at 8.00 am CET on January 10, 2025.

Attachments
Orexo announces positive topline data from clinical study of OX640 in subjects with and without allergic rhinitis