Orexo Announces FDA Acceptance of Investigational New Drug (IND) Application for OX640 for the Treatment of Anaphylaxis

- FDA accepts IND application for OX640 for the treatment of anaphylaxis, enabling initiation of pivotal clinical development program
- Needle-free epinephrine intranasal powder candidate developed using AmorphOX® demonstrated rapid absorption, good tolerability, and strong stability profile
- Clinical studies have demonstrated rapid epinephrine absorption, robust PK, and favorable tolerability
- First pivotal study planned for Q4 2026, with regulatory submission targeted for 2028

Uppsala, Sweden – September 14th 2026 – Orexo AB (publ.) **(STO:ORX) (OTCQX:ORXOY)** today announces that the U.S. Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application for OX640, a nasally administered powder formulation of epinephrine intended for the emergency treatment of anaphylaxis.

OX640 has been developed using Orexo's proprietary drug delivery platform AmorphOX® and is intended to provide rapid and reliable administration of epinephrine without the need for injection. The product is designed to address important limitations of current autoinjectors, such as needle fear, use errors, and challenges related to storage and shelf life.

The IND application is supported by extensive preclinical documentation as well as positive results from the company's completed clinical studies, which have demonstrated rapid absorption of epinephrine, a robust pharmacokinetic profile, and good tolerability. OX640 has also demonstrated very strong stability properties across a broad temperature range, potentially enabling improved shelf life compared with other products on the market and in development.

Orexo is also continuing its ongoing activities to identify a partner for the further development and commercialization of OX640. Supported by promising clinical results, strong stability data, and its proprietary AmorphOX® technology, tThe company believes that OX640 has the potential to become an attractive treatment option for patients at risk of severe allergic reactions.

In line with previous communication, Orexo plans to initiate the pivotal clinical development program during Q4 2026 and based on current plans, the OX640 NDA is expected to be ready in 2028 for regulatory submission.

CEO comment

“The IND submission for OX640 is an important milestone for Orexo and a significant step in the development of a new treatment option for patients at risk of anaphylaxis.
Although epinephrine is well established as a treatment, significant challenges remain with today’s injection-based products. With OX640, we have the opportunity to offer a needle-free, user-friendly, and temperature-stable product with the potential to improve treatment for patients worldwide,” says Nikolaj Sørensen, President and CEO of Orexo.

About OX640

OX640 is a powder-based intranasal formulation of epinephrine in clinical development for the emergency treatment of anaphylaxis. The product is based on Orexo’s proprietary AmorphOX® technology, which enables the formulation of medicines with improved stability and rapid absorption through the nasal mucosa. OX640 is being developed as a needle-free alternative to today’s epinephrine autoinjectors.

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About Orexo

Orexo is a Swedish pharmaceutical company dedicated to advance treatments for severe diseases and life-saving rescue medications to meet future healthcare needs. At the core of our innovation is AmorphOX®, a proprietary drug delivery technology that improves bioavailability and stability for both large and small molecules, enabling new approaches to administration, manufacturing, and distribution. With over 30 years of experience and multiple drugs approved globally, Orexo is advancing a diversified pipeline of programs in clinical and preclinical development. The company collaborates with partners in research, development, and commercialization. Headquartered in Uppsala, Sweden, Orexo is listed on Nasdaq Stockholm’s main market and trades as ADRs on the OTCQX market in the United States.

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