PRESS RELEASE
07 November 2023 07:00:00 CET

Egetis recruits Desiree Luthman as Vice President Global Regulatory Affairs

Stockholm, Sweden, November 7, 2023. Egetis Therapeutics AB (publ) (Nasdaq Stockholm: EGTX) today announced the recruitment of Desiree Luthman, as Vice President Global Regulatory Affairs, effective November 13, 2023. Desiree will be a member of the Company's Executive Leadership Team, and report to the CEO Nicklas Westerholm. She is based in Doylestown, Pennsylvania, USA.

Desiree has over 25 years of pharmaceutical industry experience in Global Regulatory Affairs and have successfully contributed to both FDA and EMA approvals of new drugs. Her extensive experience includes strategic regulatory responsibility covering non-clinical development, phase I-III clinical phase programs for CNS disorders, pain, inflammation, immunology, respiratory, metabolic as well as rare diseases. She has led numerous regulatory affairs teams focusing on a variety of modalities, including small molecules, biologics and gene therapy.

Prior to joining Egetis, Desiree was Senior Vice President Regulatory Affairs at Passage Bio, a US-based gene therapy company. Before that she had executive and senior regulatory affairs leadership positions at Verona Pharma, Sanofi, BMS, Celgene, Xytis and AstraZeneca. Desiree trained and practiced as a dentist before joining the pharmaceutical industry.

Nicklas Westerholm, CEO of Egetis, commented: "*I'm delighted to welcome Desiree to Egetis and proud that we have been able to attract such a talented and experienced global regulatory affairs leader to our Company. Desiree's experience in successfully leading projects to regulatory approvals with the FDA and EMA makes her ideal in the role as VP Global Regulatory Affairs at Egetis. Her global strategic regulatory affairs background will be invaluable as we embark on a truly transformational period at Egetis, with our lead investigational product Emcitate currently under review by the EMA and with the expected FDA filing in 2024.*"

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About Egetis Therapeutics

Egetis Therapeutics is an innovative and integrated pharmaceutical company, focusing on projects in late-stage development for commercialization for treatments of serious diseases with significant unmet medical needs in the orphan drug segment.
The Company's lead drug candidate *Emcitate* is under development for the treatment of patients with monocarboxylate transporter 8 (MCT8) deficiency, a highly debilitating rare disease with no available treatment. In previous studies (Triac Trial I and a long-term real-life study) *Emcitate* has shown highly significant and clinically relevant results on serum thyroid hormone T3 levels and secondary clinical endpoints. Egetis submitted a marketing authorisation application (MAA) for *Emcitate* to the European Medicines Agency (EMA) in October 2023.
After a dialogue with the FDA, Egetis is conducting a small randomized, placebo-controlled pivotal study in 16 patients to verify the results on T3 levels seen in previous clinical trials and publications. Egetis intends to submit a new drug application (NDA) in the US for *Emcitate* in mid 2024 under the Fast-Track Designation granted by FDA.
Emcitate holds Orphan Drug Designation (ODD) for MCT8 deficiency and resistance to thyroid hormone type beta (RTH-beta) in the US and the EU. MCT8 deficiency and RTH-beta are two distinct indications, with no overlap in patient populations. *Emcitate* has been granted Rare Pediatric Disease Designation (RPDD) which gives Egetis the opportunity to receive a Priority Review Voucher (PRV) in the US, after approval. This voucher can be transferred or sold to another sponsor.
The drug candidate *Aladote* is a first in class drug candidate developed to reduce the risk of acute liver injury associated with paracetamol (acetaminophen) overdose. A proof of principle study has been successfully completed and the design of the upcoming pivotal Phase IIb/III study with the purpose of applying for market approval in the US and Europe for *Aladote* has been finalized after completed interactions with FDA, EMA and MHRA and study start is planned after *Emcitate* submissions have been completed. *Aladote* has been granted ODD in the US and in the EU.
Egetis Therapeutics (STO: EGTX) is listed on the Nasdaq Stockholm main market. For more information, see www.egetis.com

Attachments

Egetis recruits Desiree Luthman as Vice President Global Regulatory Affairs