PRESS RELEASE
27 January 2023 07:00:00 CET

Egetis recruits Katayoun Welin-Berger as Vice President Operations

Stockholm, Sweden, January 27, 2023. Egetis Therapeutics AB (publ) (Nasdaq Stockholm: EGTX) today announced the recruitment of Katayoun Welin-Berger, PhD, as Vice President Operations effective March 2023. Katayoun will be a member of the Company's leadership team.

Katayoun has 30 years of experience in the pharmaceutical, probiotics and dietary supplements industries. She has a broad experience from roles of increasing responsibilities in areas including product development, CMC documentation, GMP manufacturing, procurement, outsourcing, supplier management, divestment, supply chain management and product life-cycle management. Prior to joining Egetis, Katayoun was Vice President Operations at Calliditas Therapeutics with the responsibility of designing and managing the supply chains for development candidates and commercial products, and previously she held a similar role at BioGaia. Katayoun began her career in the pharmaceutical industry at AstraZeneca and held several positions within both R&D and Operations. She obtained a PhD in Pharmacy from Uppsala University.

Nicklas Westerholm, CEO of Egetis, commented: "*I'm delighted to welcome Katayoun to Egetis. Her extensive experience and knowledge in pharmaceutical operations all the way from product development to life-cycle management of commercial products makes her an ideal candidate for this position. She will be responsible for the setup of the entire supply chains of our current development candidates and future commercial products with focus on ensuring a successful launch of Emcitate in US and Europe during 2024.*"

For further information, please contact:

Nicklas Westerholm, CEO
+46 (0) 733 542 062
nicklas.westerholm@egetis.com

Karl Hård, Head of Investor Relations & Communications
+46 (0) 733 011 944
karl.hard@egetis.com

PRESS RELEASE
27 January 2023 07:00:00 CET

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 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 T3 levels and secondary clinical endpoints. As a result of fruitful regulatory interaction Egetis intends to submit a marketing authorisation application (MAA) for *Emcitate* to the European Medicines Agency (EMA) in the first half of 2023 based on existing clinical data.
In the US, after discussions with the FDA, Egetis will conduct a small randomized, placebo-controlled 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-2023 under the Fast-Track Designation granted by FDA.
Emcitate is currently being investigated in the Triac Trial II, a Phase II/III study in very young MCT8 deficiency patients (<30 months of age) exploring potential disease modifying effects of early intervention from a neurocognitive and neurodevelopmental perspective. The recruitment target was achieved in the second quarter 2022 and 22 patients have been included in the study. Results are expected mid 2024 and are expected to be submitted post-approval to regulatory authorities.
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.
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 during 2023. *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 Katayoun Welin-Berger as Vice President Operations