

Egetis appoints Sara Melton as President of North America

Stockholm, Sweden, June 20, 2022. Egetis Therapeutics AB (publ) (Nasdaq Stockholm: EGTX) today announced the appointment of Sara Melton as President of North America. Ms. Melton will be part of the Company's leadership team and brings over 20 years of commercial leadership experience in biotechnology, pharmaceutical, and medical device companies, including rare disease. She will be responsible for establishing and maintaining a successful presence of Egetis and its products in the United States and Canada, including building the infrastructure for Egetis North America, developing relationships with key national stakeholders, and recruiting a highly effective team to support all initiatives necessary for the successful launch of *Emcitate* in 2024.

Nicklas Westerholm, CEO of Egetis, commented: "Sara has an impressive track record of success in commercial leadership including launching companies and medicines for rare diseases. I am delighted to welcome her to our team at Egetis. Sara will be responsible for initiating the establishment of a commercial infrastructure in the US for Emcitate. We are on track to submit a New Drug Application for Emcitate to the FDA in mid-2023."

Henrik Krook, VP Commercial Operations of Egetis, continued: "I am very pleased to welcome Sara to the Egetis team for the important work of ensuring successful preparations for the anticipated launch of Emcitate in the US in 2024. With her demonstrated patient focus and strong leadership skills, I am confident that impactful initiatives, such as disease awareness campaigns, diagnosis pathways and access routes, will be implemented to improve the situation for those affected by MCT8 deficiency."

Prior to joining Egetis Ms. Melton served as Vice President Commercial, Sales and Marketing Rare Disease at Mezzion Pharmaceuticals, Chicago, IL. Sara previously held various commercial leadership roles in biotechnology, pharmaceutical and medtech companies, including Astellas US LLC., Bristol-Myers Squibb, Arthrex Inc., and Achaogen Inc. Ms. Melton has an EMBA from Northwestern University, Kellogg School of Management.

Sara Melton, President North America, said: "MCT8 deficiency is a devastating disease for patients and their caregivers. I look forward to working with the passionate team at Egetis to design and execute a successful commercial strategy in the US for Emcitate and ensure a successful long-term presence of Egetis and its future products in North America."

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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 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 fully recruited 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. Results are expected in the first quarter of 2024 and are expected to be submitted post-approval to regulatory authorities shortly thereafter.

Emcitate holds Orphan Drug Designation (ODD) for MCT8 deficiency and resistance to thyroid hormone type beta (RTH- #) in the US and the EU. *Emcitate* has been granted Rare Pediatric Disease Designation (RPD) 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) poisoning. 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. *Aladote* has been granted ODD in the US and an application for ODD was submitted in the EU in the first quarter of 2021. There is an ongoing dialogue with EMA on the appropriate scope of the indication for an ODD in the EU.

Egetis Therapeutics (STO: EGTX) is listed on the Nasdaq Stockholm main market. For more information, see www.egetis.com

Attachments

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