PRESS RELEASE
13 October 2022 08:00:00 CEST

Egetis presents significant progress towards market at Capital Markets Day today

Stockholm, Sweden, October 13, 2022. Egetis Therapeutics AB (publ) (Nasdaq Stockholm: EGTX) is today hosting a Capital Markets Day from 1:00pm-4:00pm CEST at Erik Penser Bank, Apelbergsgatan 27, Stockholm, Sweden, for investors, analysts and media. The event is now fully subscribed for in-person attendance, but it can be followed via a live Webcast from this LINK.

Egetis' Capital Markets Day will feature a presentation by Dr Edward Visser, Erasmus Medical Center, Rotterdam, The Netherlands, on the unmet medical need and the clinical manifestations of the debilitating disease MCT8 deficiency as well as the positive clinical experience with Egetis' lead drug candidate *Emcitate* (tiratricol) treating this condition. Furthermore, a presentation by Professor James Dear, Edinburgh University, Scotland, on the significant burden of paracetamol overdosing and the clinical experience with Egetis' drug candidate *Aladote* (calmangafodipir). In addition, members of Egetis' leadership team and Board will highlight the significant progress made by Egetis towards marketing approvals of *Emcitate* and *Aladote*, and the ongoing commercial build out and launch activities. Nicklas Westerholm, CEO at Egetis, will also present Egetis near term strategic objectives and long-term ambitions.

Nicklas Westerholm, CEO at Egetis, said: "I'm delighted to welcome Egetis' world-leading academic collaborators in their respective field, Dr Edward Visser and Professor James Dear, to present at our Capital Markets Day today. It's also a pleasure to reflect on how far Egetis has progressed since its formation two years ago. We are well on track to submit a marketing authorisation application in EU in the first half of next year and a new drug application in the US mid-2023 for our lead drug candidate *Emcitate* paving the way for a launch in 2024."

Live webcast: Please follow this link

A recording of the event will also be made available on **www.egetis.com**

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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 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 in the first half 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-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 for later in 2022. *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

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