PRESS RELEASE
23 May 2023 21:02:00 CEST

Egetis announces termination of discussions regarding a potential acquisition of the Company and provides a corporate update

Stockholm, Sweden, May 23, 2023. Further to the announcement published on March 30, 2023, in response to certain market rumors, the Board of Directors of Egetis Therapeutics AB (publ) (STO: EGTX) (the "Company") wishes to make the following statement: Discussions, which were triggered by an unsolicited approach by an external party, have taken place between certain external parties and Egetis regarding a potential acquisition of the Company. These discussions have now been terminated as the Board believes the contemplated offer and terms, while providing a premium to the current share price, considerably undervalued the long-term prospects of the Company. The Company will continue to focus on delivering the strategy outlined at its Capital Markets Day on October 13, 2022 [LINK]. As a consequence of this intense process and discussions, the timeline for the submission of the marketing authorisation application (MAA) for *Emcitate* (tiratricol) to the European Medicines Agency (EMA) has been extended from the second quarter to the early autumn of 2023. Nonetheless, the Company remains confident that *Emcitate* is on track for expected regulatory approvals and launches in both EU and USA during 2024.

Thomas Lönngren, Chairman of the Board of Directors of Egetis, said: *"We are in a transformative period for the Company, with several near-term value creating milestones and the Board of Egetis believes that the strategy to build an independent sustainable rare-disease company with the ambition to bring unique therapies to patients with rare diseases to extend and improve quality of life remains the most long-term value creating alternative for our shareholders."*

Nicklas Westerholm, CEO of Egetis, continued: *"There is a huge unmet medical need to treat patients suffering from MCT8 deficiency and it is a key priority for Egetis to bring Emcitate to market as the first treatment available for these patients. Because of the intense process and discussions with external parties regarding a potential acquisition, the EMA submission for Emcitate is now expected in the early autumn of 2023. I'm also looking forward to the first patient being enrolled in the ReTRIACt trial in the second quarter of this year. We remain on track for expected regulatory approvals and launches in both EU and USA during next year as planned and continue the stepwise build-up of our commercial and medical affairs capabilities in preparation for these launches."*

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This information is information that Egetis Therapeutics is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-05-23 21:02 CEST.

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. As a result of regulatory interaction Egetis intends to submit a marketing authorisation application (MAA) for *Emcitate* to the European Medicines Agency (EMA) during the early autumn of 2023 based on existing clinical data.
After a dialogue 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 the fourth quarter of 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 mid 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. 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 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

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