PRESS RELEASE
28 June 2023 23:30:00 CEST

Egetis announces site activation in the pivotal ReTRIACt trial for Emcitate® and updates timeline for the US NDA submission

Company to host a webcast at 3.00 pm CEST (9.00 am EDT) tomorrow June 29

Stockholm, Sweden, June 28, 2023. Egetis Therapeutics AB (publ) (Nasdaq Stockholm: EGTX) today announced that the first site has been activated in the pivotal ReTRIACt clinical trial for the new drug application (NDA) in the USA for *Emcitate*. The Company further announced that it now expects topline results from the ReTRIACt study during the first half of 2024 and estimates subsequent NDA submission in the USA in mid-2024, under the fast-track designation. The updated timelines are due to the substantial delay in the study start, and an anticipated higher number of treatment naive patients, which implies a longer trial duration per patient, expected to be recruited in the trial, compared to the original assumptions. As a consequence of the delay, the build-up of the commercial infrastructure in the US will be aligned with the updated NDA submission timelines and all resources will be focused on the *Emcitate* ReTRIACt study and the upcoming EU submission. Therefore, the in-house development of *Aladote* will be parked, until *Emcitate* submissions have been completed.

The ReTRIACt clinical trial is a pivotal, 16 patients, randomized, placebo-controlled trial for the US NDA for *Emcitate*, which is being developed for the treatment of monocarboxylate transporter 8 (MCT8) deficiency. The trial will be conducted across three centers at the Erasmus Medical Center, Rotterdam, the Netherlands, Children's Hospital of Philadelphia, Philadelphia, PA, USA, and Addenbrooke's Hospital, Cambridge, UK.

The Company is working diligently with the trial sites to facilitate a smooth and efficient execution of the trial and more than 30 eligible patients have been identified across the three participating sites. In the meantime, the Company continues to finalize the dossier for the MAA in the EU for *Emcitate* for submission in the early autumn of 2023.

Nicklas Westerholm, CEO of Egetis, commented: "I look forward to the start of the ReTRIACt trial for *Emcitate*, but I recognize it has taken a long time to initiate the trial, caused by multiple administrative delays over the past six months. We remain focused on working diligently with the three trial sites to now facilitate a smooth and efficient execution of the trial with our resources directed to the *Emcitate* ReTRIACt study and the upcoming EU submissions. Our disease awareness activities are bearing fruit and we have identified a large number of treatment naïve patients, primarily in the USA, that could now be eligible for this trial. While positive long-term, both for the patients and for the Company, in the shorter perspective this implies a longer trial duration per patient, which extends the timeline to completion of the study and subsequent submission in the US. For the EU, I look forward to our progress towards submitting the MAA for *Emcitate* in the early autumn of 2023 as previously communicated."

Webcast information:
If you wish to participate via webcast please use the link below. Via the webcast you are able to ask written questions.
https://ir.financialhearings.com/egetis-pressconference-2023

If you wish to participate via teleconference please register on the link below. After registration you will be provided phone numbers and a conference ID to access the conference. You can ask questions verbally via the teleconference.
https://conference.financialhearings.com/teleconference/?id=5005365

About the ReTRIACt trial

PRESS RELEASE
28 June 2023 23:30:00 CEST

The ReTRIACt trial (clinicaltrials.gov identifier NCT05579327) is a double-blind, randomized Phase 3 multicenter placebo-controlled study in 16 evaluable male participants diagnosed with MCT8 deficiency. Participants, from 4 years of age and having demonstrated stable maintenance treatment with *Emcitate*, will be randomized to receive placebo or *Emcitate* for 30 days or until reaching rescue criterion (serum total triiodothyronine [T3] above upper limit of normal [ULN] of the participant's normal range, for a sample collected during the 30-day Randomized Treatment Period). The research hypothesis to be tested is that, for participants in the placebo group, removal of *Emcitate* will lead to an increase of serum total T3 concentration above the ULN and requirement of rescue treatment with *Emcitate*, compared to those who continue to receive tiratricol.

For further information, please contact

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

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

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 2023-06-28 23:30 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 mid 2024 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.
Egetis Therapeutics (STO: EGTX) is listed on the Nasdaq Stockholm main market. For more information, see www.egetis.com

PRESS RELEASE
28 June 2023 23:30:00 CEST

Attachments

Egetis announces site activation in the pivotal ReTRIACt trial for Emcitate® and updates timeline for the US NDA submission