PRESS RELEASE
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Egetis highlights recent major milestones, status of ReTRIACt trial and gives a corporate update at Investor Day in Stockholm today

Stockholm, Sweden, December 19, 2023. Egetis Therapeutics AB (publ) ("**Egetis**" or the "**Company**") (Nasdaq Stockholm: EGTX), is today hosting an Investor Day in Stockholm.

The event will feature presentations by Dr Andrew Bauer, Children's Hospital of Philadelphia, on monocarboxylate transporter 8 (MCT8) deficiency and the unmet medical need, and Dr Carla Moran, University College Dublin, on a separate indication called resistance to thyroid hormone beta (RTH-beta) and the unmet medical need in this disease. In addition, members of Egetis' management team will highlight the significant progress made by Egetis towards marketing approvals of *Emcitate* (tiratricol), including an update of the status of the ReTRIACt trial, and the plans for prelaunch activities and commercialization focusing on disease awareness, market access and value proposition. Nicklas Westerholm, CEO at Egetis, will also present the Company's near-term strategic objectives and long-term ambitions.

During the last few months Egetis has achieved major milestones that have been transformational for the Company. These include the Marketing Authorisation Application for *Emcitate* for MCT8 deficiency in the EU, filed on October 9. This was followed by the SEK 462 million combined equity and debt financing announced on October 10, comprising a SEK 172 million equity private placement, at a premium, and SEK 290 million debt financing. The SEK 172 million private placement was led by US healthcare investor Frazier Life Sciences for a subscribed amount of SEK 155 million, with demand for the new shares significantly exceeding the size of the private placement. Frazier Life Sciences has a track record of partnering with science-driven healthcare businesses and Egetis is delighted to have attracted them as an important new strategic shareholder. Finally, on November 10 the Company entered into an exclusive license agreement with Fujimoto Pharmaceutical Corporation to develop and commercialize *Emcitate*, for the treatment of MCT8 deficiency, in Japan. Fujimoto will finance the necessary development in Japan and be responsible for regulatory interactions. Egetis retains significant share, approximately one third, of future revenues in Japan.

During the Investor Day the Company will also give an update on the progress made in the ReTRIACt trial, which is pivotal for the New Drug Application (NDA) in the US. The first site (participating hospital) in the trial was initiated end of June 2023 and the first patient was recruited in July 2023. As of today, the ReTRIACt trial has recruited 7 patients, out of a target of 16 evaluable patients, at the two sites actively recruiting since July and August, respectively. One additional site started recruiting mid-December and a fourth site is expected to start recruiting in January 2024. There are 27 eligible patients identified for the remaining recruitment, consisting of 8 on-treatment and 19 treatment-naïve patients. As previously communicated, there are several factors affecting the completion of the ReTRIACt trial, such as site initiations and the recruitment capacity per month at the participating sites, the ability of the patients' families to travel and the higher proportion of treatment naïve patients, which require a longer run-in period than patients on treatment. Egetis has taken steps to mitigate these factors and will update the market as soon as recruitment has been completed and at that point inform about the timing of availability of top-line results, and the expected timing of the subsequent NDA filing.

There is a continued large and increasing interest from physicians all over the world to treat patients suffering from MCT8-deficiency with *Emcitate*, and it is already being made available as part of different Managed Access Programs to patients in over 25 countries. In total, over 190 patients are now being treated with *Emcitate*, and more and more patients are gaining access to treatment, a true testimony of the unmet medical need for these patients. The Company has focused its activities on improving

disease awareness and diagnosis, including participation and dialogues at scientific conferences, patient identification partnerships with genetic testing companies, Key Opinion Leader engagements, advisory boards, and interactions with Patient Advocacy Groups. This has resulted in the identification of an additional 50 MCT8 deficiency patients in the USA, previously not diagnosed or known to the Company.

Egetis' strategy to build a sustainable rare-disease company also explores opportunities to extend the use of *Emcitate* into other indications, like RTH-beta, which is a separate condition, with a non-overlapping patient population to MCT8 deficiency. As previously announced, the Company has parked the development of the Phase 3 ready Albatross study for *Aladote* for the prevention of acute liver injury caused by paracetamol/ acetaminophen poisoning, until the regulatory submissions for *Emcitate* for the treatment of MCT8 deficiency have been completed. Furthermore, the Company is also evaluating possible new assets that would fit into its strategy of developing late-stage rare disease assets for marketing approval and commercialization.

Nicklas Westerholm, CEO of Egetis, commented: *"The past few months have been transformative for Egetis. In July, we recruited the first patients for the Phase 3 clinical trial ReTRIACt, which is pivotal for the New Drug Application (NDA) in the USA. As of today, we have recruited seven patients in the trial from two sites actively recruiting during the autumn. It is promising to see that two additional sites are initiating recruitment, which should lead to faster recruitment going forward. We will update the market as soon as recruitment has been completed and at that point inform about the timing of availability of top-line results, and the expected timing of the subsequent NDA filing. I am pleased that in early October, we submitted a marketing authorisation application (MAA) for Emcitate for the treatment of MCT8 deficiency with the European Medicines Agency (EMA). I'm delighted that we have secured long-term financing and a new strategic shareholder in Frazier Life Sciences. Finally, in November we signed a licensing agreement for Emcitate in Japan with Fujimoto. We are now in a good position to continue our work to bring Emcitate to the market, as the first treatment for patients with MCT8 deficiency."*

For further information, please contact:

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

Karl Hård, Head of Investor Relations & Business Development
+46 (0) 733 011 944
karl.hard@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 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. Egetis submitted a marketing authorisation application (MAA) for *Emcitate* to the European Medicines Agency (EMA) in October 2023.
After a dialogue with the FDA, Egetis is conducting a small randomized, placebo-controlled pivotal 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* under the Fast-Track Designation granted by FDA.
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 after *Emcitate* submissions have been completed. *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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