PRESS RELEASE
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For investors and media only

Egetis Confirms Launch of Emcitate® in Germany

Stockholm, Sweden, May 5, 2025. Egetis Therapeutics AB (publ) ("Egetis" or the "Company") (NASDAQ Stockholm: EGTX), a pharmaceutical company dedicated to developing therapies for treatments of serious diseases with significant unmet medical needs in the orphan drug segment, today confirms the availability of its first approved product, Emcitate® (tiratricol) in Germany, as of May 1. This follows the European Commission's approval of Emcitate® on February 13, 2025 for the treatment of MCT8 deficiency – a rare and serious condition. Emcitate® is the first and only approved treatment in the EU for MCT8 deficiency.

Nicklas Westerholm, CEO of Egetis, commented: *"The EU approval and now the first commercial launch of Emcitate in Germany are historical milestones for Egetis and for the entire MCT8 deficiency community.*

"I am incredibly proud of what our team and partners have accomplished. Bringing the first and only approved treatment for this devastating condition to patients is the result of years of dedication, innovation, and belief in our mission. A heartfelt thank you goes to everyone who made this possible – especially to Professor Edward Visser and his team at Erasmus University Medical Center in Rotterdam, the Netherlands. Today marks the beginning of a new chapter for patients and families across Europe."

The German launch marks a major step in Egetis' journey from an emerging biotech to a commercial-stage company. It is the first of several planned launches in EU with initial focus on the EU4 countries – Germany, France, Spain, and Italy – with pricing and reimbursement dossiers submitted in both Germany and France.

Since acquiring the rights to Emcitate, Egetis has made significant scientific, clinical, and manufacturing investments, totaling over EUR 100 million, to advance Emcitate® from concept to commercialization. These include:

- **Clinical Development**: Sponsoring two key clinical trials to demonstrate efficacy and safety in patients with MCT8 deficiency and bioavailability / bioequivalence in healthy volunteers, alongside an ongoing pivotal trial supporting the upcoming New Drug Application (NDA) to the US FDA.
- **Non-Clinical Studies**: Execution of comprehensive *in vivo* and *in vitro* studies to satisfy safety requirements.
- **Formulation Development**: Development of a new patient-friendly tablet to meet regulatory requirements and current quality standards. The new tablet also offers greater delivery convenience for patients and caregivers.
- **Manufacturing Upgrades**: Major investments in manufacturing infrastructure to meet current Good Manufacturing Practice (GMP) and regulatory standards.

Broad Access and Future Vision

Egetis is committed to ensuring patients have access to Emcitate as quickly and equitably as possible. As part of this mission, it has implemented one of the largest managed access programs relative to its size, providing early access to over 230 patients in more than 25 countries.

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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.

On February 13, 2025, the European Commission approved Emcitate® (tiratricol) as the first and only treatment for MCT8 deficiency in EU.

The Company's lead drug candidate Emcitate® (tiratricol) is under development for the treatment of patients with monocarboxylate transporter 8 (MCT8) deficiency, a highly debilitating rare disease with no available treatment.

After a dialogue with the FDA, Egetis is conducting a randomized, placebo-controlled pivotal study in at least 16 evaluable patients to verify the results on T3 levels seen in previous clinical trials and publications. As previously communicated, the Company will update the market as soon as recruitment closes, and at that time, the Company will also provide information on when to expect topline results and when the Company plans to submit the NDA application in 2025.

Tiratricol 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. Tiratricol 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® (calmangafodipir) 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. The design of a pivotal Phase IIb/III study (Albatross), with the purpose of applying for market approval in the US and Europe, has been finalized following interactions with the FDA, EMA and MHRA. The development program for calmangafodipir has been parked until Emcitate marketing authorization submissions for MCT8 deficiency have been completed in the EU and the USA. Aladote has been granted ODD in the US and in the EU.

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

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Attachments

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