

## Egetis submits a patent application to the United States Patent and Trademark Office for “Processes of Preparation” of tiratricol

**Stockholm, Sweden, September 19, 2024.** Egetis Therapeutics AB (publ) (“Egetis” or the “Company”) (Nasdaq Stockholm: EGTX), today announced that it has submitted a patent application to the United States Patent and Trademark Office (USPTO) for “Processes of Preparation” of tiratricol. If granted, this would be a significant patent Egetis has obtained for the investigational drug tiratricol.

Tiratricol is an endogenously available metabolite of thyroid hormone, with similar bioactive properties as the active thyroid hormone T3. Tiratricol enters the cell independently of the monocarboxylate transporter 8 (MCT8), bypassing the pathophysiologic defect in MCT8 deficiency. Clinical trials for the use of tiratricol for the treatment of MCT8 deficiency are ongoing and in October 2023 Egetis submitted a marketing authorisation application (MAA) in the EU. Accordingly, new and more efficient synthetic routes leading to tiratricol are needed. The processes and compounds described in the patent application help meet these and other needs.

Egetis holds Orphan Drug Designation (ODD) for Emcitate® (tiratricol) for MCT8 deficiency in the US and the EU, which currently provides marketing exclusivities of 7 and 10 years, respectively, from the dates of regulatory approvals. Generally, the exclusivity term of a new patent is 20 years from the date on which the application for the patent was filed in the United States.

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## About Egetis Therapeutics

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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*® (tiratricol) 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 randomized, placebo-controlled pivotal study in 16 evaluable patients to verify the results on T3 levels seen in previous clinical trials and publications. Egetis 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.

*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*® (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 study start has been postponed until *Emcitate* marketing authorization submissions for MCT8 deficiency 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](http://www.egetis.com)

## Attachments

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