PRESS RELEASE
17 July 2024 08:48:00 CEST

European Thyroid Association recommends tiratricol (Emcitate®) as long-term therapy for all patients with MCT8 deficiency in new guidelines

Stockholm, Sweden, July 17, 2024. Egetis Therapeutics AB (publ) ("Egetis" or the "Company") (Nasdaq Stockholm: EGTX), today announced that the European Thyroid Association (ETA) has published new guidelines recommending the use of tiratricol (TRIAC or Emcitate®) as long-term therapy for all patients with MCT8 deficiency, and for certain patients with Resistance to Thyroid Hormone (RTH)-beta, as further outlined in the guidelines.

There are currently no approved treatments for MCT8 deficiency or RTH-beta. Egetis has obtained orphan drug designation for tiratricol for the treatment of MCT8 deficiency and RTH-beta in the EU and the USA, and has submitted a marketing authorisation application in the EU, which is currently under review by the European Medicines Agency.

These inaugural *2024 European Thyroid Association Guidelines on diagnosis and management of genetic disorders of thyroid hormone transport, metabolism and action* were commissioned by the Executive Committee of the ETA and developed by an independent team of experts. The guidelines can be accessed here:

https://etj.bioscientifica.com/view/journals/etj/aop/etj-24-0125/etj-24-0125.xml

Nicklas Westerholm, CEO, Egetis Therapeutics, commented: *"MCT8 deficiency is a detrimental condition with significant unmet medical need. It's really encouraging to note that the European Thyroid Association recommends tiratricol (Emcitate®) as long-term therapy for all patients with MCT8 deficiency. Our Marketing Authorisation Application in the EU for tiratricol for the treatment of MCT8 deficiency was submitted in October 2023 and we look forward to providing the first potential approved treatment for patients with MCT8 deficiency."*

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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® (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

Attachments

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