PRESS RELEASE
14 August 2024 08:00:00 CEST

Egetis submits responses to the European Medicines Agency's Day 120 List of Questions for the Marketing Authorisation Application for tiratricol (Emcitate®)

Stockholm, Sweden, August 14, 2024. Egetis Therapeutics AB (publ) ("**Egetis**" or the "**Company**") (Nasdaq Stockholm: EGTX), today announced that the Company has submitted responses to the Day 120 List of Questions received from the European Medicines Agency for the Marketing Authorisation Application (MAA) for tiratricol (Emcitate®) for the treatment of MCT8 deficiency. The next expected step in the review process, the Day 180 list of outstanding issues, is expected in October 2024.

Nicklas Westerholm, CEO, Egetis Therapeutics, commented: "*The timely responses to EMA's Day 120 list of questions for our marketing authorisation application for tiratricol (Emcitate®) is an important milestone for Egetis. There is currently no approved treatment for patients with MCT8 deficiency. I'm delighted that the submission team at Egetis has been able to address all questions from EMA and we look forward to continuing the dialogue with EMA in October.*"

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

PRESS RELEASE
14 August 2024 08:00:00 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® (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

Egetis submits responses to the European Medicines Agency's Day 120 List of Questions for the Marketing Authorisation Application for tiratricol (Emcitate®)