PRESS RELEASE
27 March 2026 16:42:00 CET

Egetis Announces FDA Acceptance and Priority Review of NDA for Emcitate® (tiratricol) for MCT8 Deficiency

- NDA submission for Emcitate® successfully validated by the FDA
- Priority Review granted and PDUFA target action date set to September 28, 2026
- Emcitate® (tiratricol) is eligible to receive a Priority Review Voucher (PRV) upon approval
- If approved, Emcitate® (tiratricol) would become the first approved treatment in the United States for MCT8 deficiency

Stockholm, Sweden, March 27, 2026. Egetis Therapeutics AB (publ) ("Egetis" or the "Company") (NASDAQ Stockholm: EGTX), today announced that the U.S. Food and Drug Administration (FDA) has accepted the filing of its New Drug Application (NDA) for Emcitate® (tiratricol) for the treatment of MCT8 deficiency. Egetis completed the rolling NDA in January 2026. The application has been granted Priority Review and assigned a Prescription Drug User Fee Act (PDUFA) target action date, or FDA decision date, of September 28, 2026.

Nicklas Westerholm, CEO of Egetis, commented: *"MCT8 deficiency is a rare, devastating, life-shortening disorder with no approved treatment in the U.S. The acceptance of our NDA with Priority Review represents an important step in the path to making Emcitate® (tiratricol) available to MCT8 deficiency patients in the U.S. The Priority Review also highlights the robust dataset we have in this rare genetic disease, with the NDA based on results from Triac Trial I, Triac Trial II, ReTRIACt, EMC Cohort Study, EMC Survival Study and the U.S. Expanded Access Program. We look forward to collaborating with the FDA during the NDA Priority Review process and will in parallel continue to build our medical affairs and market access capabilities towards a potential U.S. launch in the fourth quarter of this year."*

A Priority Review will direct overall attention and resources to the evaluation of applications for drugs that, if approved, would represent significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. A Priority Review means FDA's goal is to take action on an application within 6 months, compared to 10 months under standard review.

Emcitate® (tiratricol) has previously been granted Rare Pediatric Disease Designation by the FDA and is eligible to receive a Priority Review Voucher (PRV) upon approval, and a PRV was consequently requested in connection with the submission. The transferability of PRVs has created an active secondary market for these vouchers, selling for $150-$205 million per voucher in 2025/26.

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This information is information that Egetis Therapeutics is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2026-03-27 16:42 CET.

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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 developed for the treatment of patients with monocarboxylate transporter 8 (MCT8) deficiency, a highly debilitating rare disease with no available treatment. In February 2025 the European Commission approved Emcitate® as the first and only treatment for MCT8 deficiency in EU. Egetis initiated the launch of Emcitate® in Germany on May 1, 2025. Emcitate® (tiratricol) is not approved in the USA.

The Company completed a rolling New Drug Application (NDA) for Emcitate® (tiratricol) in the USA on January 29, 2026. The FDA is expected to confirm within 60 days that the NDA submission is complete. As a designated Fast Track and Breakthrough Therapy, Egetis has requested Priority Review, and if granted, the FDA review should be completed within six months following the 60-day filing review period.

Based on feedback from the FDA, the NDA for Emcitate® (tiratricol) for treatment of MCT8 deficiency will be based on currently available clinical data from Triac Trial I, Triac Trial II, ReTRIACt, EMC Cohort Study, EMC Survival Study and the US Expanded Access Program.

Tiratricol holds Orphan Drug Designation (ODD) for MCT8 deficiency and resistance to thyroid hormone 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 Breakthrough Therapy Designation and Rare Pediatric Disease Designation (RPDD) by the FDA, which gives Egetis the opportunity to receive a Priority Review Voucher (PRV) in the US, after approval.

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 Aladote® has been parked. Aladote® has been granted ODD in the US and in the EU.

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

Attachments

Egetis Announces FDA Acceptance and Priority Review of NDA for Emcitate® (tiratricol) for MCT8 Deficiency