PRESS RELEASE
09 March 2026 07:00:00 CET

Egetis Receives Notice of Allowance for MCT8 Deficiency Composition Patent in the U.S.

Stockholm, Sweden, March 9, 2026. Egetis Therapeutics AB (publ) ("Egetis" or the "Company") (NASDAQ Stockholm: EGTX) today announced that the United States Patent and Trademark Office (USPTO) has issued a Notice of Allowance for the Company's patent application No. 19/261,360 entitled "Pharmaceutical Compositions for Treating MCT8 Deficiency". Now that Egetis have paid the issue fee, this Notice of Allowance is expected to result in the issuance of a U.S. patent once administrative processes are completed.

The allowed patent provides protection for a novel composition, which contains tiratricol as the active ingredient, designed to correct the disrupted thyroid hormone signaling characteristic of MCT8 deficiency. The allowed claims cover, among other things, a method of treating MCT8 deficiency with a pharmaceutical composition that encompasses tiratricol, including dosing regiments, and tiratricol compositions with specific excipients. This Notice of Allowance represents a significant milestone in strengthening the Company's intellectual property portfolio supporting its lead investigational therapy. Egetis expects the resulting patent will be Orange Book-listable, with an anticipated expiration date of 2045.

Nicklas Westerholm, CEO, said: *"We are very pleased to receive this Notice of Allowance, which reinforces the innovative nature of our therapeutic approach for patients with MCT8 deficiency. This accomplishment supports our commitment to advancing a much-needed treatment option for this devastating disorder."*

Egetis also intends to seek corresponding patent protection in additional territories around the World, including Europe and Japan, based on a PCT International Patent Application that the Company has filed.

Egetis has submitted a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for Emcitate® (tiratricol) for the treatment of MCT8 deficiency 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. Thus, Egetis anticipates regulatory decision on the NDA application in September 2026.

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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

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