PRESS RELEASE
May 5, 2026 08:00:00 CEST

Egetis Announces Grant of Patent for MCT8 Deficiency Composition in the U.S.

Stockholm, Sweden, May 5, 2026. Egetis Therapeutics AB (publ) ("Egetis" or the "Company") (NASDAQ Stockholm: EGTX) today announced that the United States Patent and Trademark Office (USPTO) granted Patent No. US 12611383B1 for the Company's patent application No. 19/261,360 entitled "Pharmaceutical Compositions for Treating MCT8 Deficiency".

The newly granted 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 claims cover, among other things, a method of treating MCT8 deficiency with the claimed pharmaceutical composition that encompasses tiratricol, dosing regiments, and tiratricol compositions with specific excipients. This patent represents a significant milestone in strengthening the Company's intellectual property portfolio. Egetis expects the granted patent will be Orange Book-listable. The patent has an expiration date of 2045.

Nicklas Westerholm, CEO, said: *"The grant of this patent represents an important milestone in strengthening the intellectual property protecting Emcitate® (tiratricol). If approved in the U.S., Emcitate® is expected to benefit from statutory 7-year orphan drug exclusivity in addition to patent protection."*

As previously communicated, 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.

Emcitate® (tiratricol) has been granted Breakthrough Therapy, Orphan Drug, Fast Track, and Rare Pediatric Disease Designations by the U.S. Food and Drug Administration (FDA). On March 27, 2026, the FDA accepted the filing of Egetis' New Drug Application (NDA) for Emcitate® (tiratricol) for the treatment of MCT8 deficiency. The application has been granted Priority Review and assigned a Prescription Drug User Fee Act (PDUFA) target action date of September 28, 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.

On March 27, 2026, Egetis 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. 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.

The NDA for Emcitate® (tiratricol) for treatment of MCT8 deficiency is based on 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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