PRESS RELEASE
16 February 2026 07:00:00 CET

Egetis provides update on progress with the development of Emcitate® (tiratricol) for MCT8 deficiency in Japan

Stockholm, Sweden, February 16, 2026. Egetis Therapeutics AB (publ) ("Egetis" or the "Company") (NASDAQ Stockholm: EGTX), today announced that its Japanese partner Fujimoto Pharmaceuticals, who has an exclusive license from Egetis for the development and commercialization of Emcitate® (tiratricol) for monocarboxylate transporter 8 (MCT8) deficiency in Japan, recently had a Pre-application consultation for drugs with the Japan's Pharmaceuticals and Medical Devices Agency (PMDA) regarding the regulatory pathway and data package for the marketing application of Emcitate®.

As of October 2024, new guidelines from Japan's Ministry of Health, Labour and Welfare allow for approval without Japanese patient clinical data for ultra-rare diseases, where conducting clinical trials in Japan is impracticable, provided that global trial data is robust and the benefit-risk ratio is favorable. The New Drug Application (NDA) in Japan for Emcitate® for treatment of MCT8 deficiency is expected to utilize existing data generated from the global clinical development program. Egetis and Fujimoto are evaluating the submission timelines for the NDA.

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

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

Attachments

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