PRESS RELEASE
August 31, 2026 08:00:00 CEST

Tiratricol Granted Orphan Drug Designation for MCT8 Deficiency in Japan

Stockholm, Sweden, August 31, 2026. Egetis Therapeutics AB (publ) ("Egetis" or the "Company") (NASDAQ Stockholm: EGTX), today announced that its partner Fujimoto Pharmaceutical Corporation, which has an exclusive license agreement to develop and commercialize Emcitate® (tiratricol) for the treatment of MCT8 deficiency in Japan, has been granted Orphan Drug Designation (ODD) for tiratricol for MCT8 deficiency by the Ministry of Health, Labour and Welfare (MHLW).

One of the benefits of ODD in Japan is that a marketing authorization application is eligible for Priority Review, reducing the review time from approximately twelve to nine months and an extension of the market exclusivity period to ten years.

Emcitate (tiratricol) also holds ODD for MCT8 deficiency in the US and EU.

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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. EU product information can be accessed via the Summary of Product Characteristics found here.

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. Emcitate® (tiratricol) is not approved in the USA.

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

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Forward-looking statements

This press release contains forward-looking statements within the meaning of applicable securities laws, including statements regarding the commercialization and availability of Emcitate® (tiratricol) in the United States, the timing and outcome of potential monetization of the Rare Pediatric Disease Priority Review Voucher, the expected capabilities of the Company's patient access and distribution infrastructure, the anticipated benefits of Emcitate for patients with MCT8 deficiency, and the Company's broader strategic plans for the development and commercialization of therapies for rare diseases. Forward-looking statements can generally be identified by words such as "expects," "anticipates," "intends," "believes," "estimates," "plans," "will," "may," "could," "potential," or similar expressions, although not all forward-looking statements contain these words.

These statements are based on the Company's current expectations, assumptions, and assessments as of the date of this press release and are subject to risks, uncertainties, and other factors that could cause actual results to differ materially from those expressed or implied. Such factors include, but are not limited to: risks related to the commercial launch and market acceptance of Emcitate in the United States; the ability to establish and maintain adequate commercial infrastructure, including distribution, patient support, and reimbursement arrangements; the timing and terms of any monetization of the Priority Review Voucher, which is subject to market conditions and the availability of interested purchasers; potential post-marketing requirements or restrictions imposed by the FDA; the ability to maintain regulatory approvals in the United States and the European Union; competition from existing or future therapies; the Company's ability to secure adequate funding for its operations and commercial activities; and general economic, market, and business conditions.

For a further description of risks and uncertainties that could affect the Company's business and results, reference is made to the Company's most recent annual report and other filings with relevant regulatory authorities available at www.egetis.com. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by applicable law or regulation.

Attachments

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