PRESS RELEASE
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FDA's rare pediatric disease priority review program extended until 2029

Stockholm, Sweden, February 4, 2026. Egetis Therapeutics AB (publ) ("Egetis" or the "Company") (NASDAQ Stockholm: EGTX), today noted that the U.S. Food and Drug Administration's (FDA's) Rare Pediatric Disease Priority Review program has been prolonged from its previous sunset deadline on September 30, 2026 until September 30, 2029. This prolongation was part of the *Mikaela Naylon Give Kids a Chance Act,* which was adopted by Congress as part of the Congressional Bill H.R. 7148 and signed into law on February 3, 2026.

Egetis' investigational drug Emcitate® (tiratricol) has been granted Rare Pediatric Disease Designation by the FDA, which makes Egetis eligible to receive a Priority Review Voucher (PRV), upon approval. As previously announced, Egetis completed its rolling U. S. New Drug Application (NDA) submission on January 29, 2026 and expects a regulatory decision from the FDA in September 2026.

FDA's PRV program, established in 2012 and subsequently reauthorized in 2017 and 2020, is designed to stimulate the development of therapies for conditions that typically receive limited research investment, including rare pediatric diseases. Through the program, a company that obtains FDA approval for an eligible therapy is awarded a voucher that can be used to secure priority review for a future NDA or Biologics License Application (BLA). Priority review shortens the FDA's standard review period from ten months to approximately six months. PRVs are transferable and can be sold to other companies, creating an active secondary market for these vouchers. In 2025 PRVs were sold for $150-$200 million per voucher.

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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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