PRESS RELEASE
September 28, 2026 23:45:00 CEST

Egetis Therapeutics Announces U.S. FDA Approval of EMCITATE® (tiratricol) for Patients with MCT8 Deficiency

- **First and only FDA-approved treatment of peripheral thyrotoxicosis in adults and pediatric patients with monocarboxylate transporter 8 (MCT8) deficiency in the United States**
- **Egetis launches Egetis RareLink™, the EMCITATE patient support program, in partnership with PANTHERx® Rare**
- **FDA granted Egetis a Rare Pediatric Disease Priority Review Voucher (PRV) in connection with the approval**
- **Egetis to host a conference call and webcast for analysts and investors on Tuesday September 29 at 8:00 am CEST (2:00 am EDT)**

STOCKHOLM, SWEDEN, September 28, 2026. – Egetis Therapeutics AB (publ) ("Egetis" or the "Company") (Nasdaq Stockholm: EGTX) today announced that the U.S. Food and Drug Administration (FDA) has approved EMCITATE® (tiratricol), a thyroid hormone receptor agonist, for the treatment of peripheral thyrotoxicosis in adults and pediatric patients with monocarboxylate transporter 8 (MCT8) deficiency (Allan–Herndon–Dudley syndrome). EMCITATE is not recommended for the treatment of primary hypothyroidism. EMCITATE is the first FDA-approved treatment option for patients with MCT8 deficiency in the United States.

MCT8 deficiency is a rare, devastating, life-limiting, X-linked disorder caused by pathogenic mutations in the *SLC16A2* gene. These mutations impair the function of MCT8, a critical cell-surface thyroid-hormone transporter responsible for thyroid hormone transport in specific cells, including in the brain. As a result, patients experience disrupted thyroid hormone signaling, characterized by insufficient thyroid hormone activity in the central nervous system and excessive exposure to the active thyroid hormone triiodothyronine (T3) in peripheral tissues. This leads to a complex disorder characterized by severe neurodevelopmental impairment and persistent peripheral thyrotoxicosis. Patients with MCT8 deficiency have a reported median life expectancy of approximately 35 years. For further details, please see 'About MCT8 deficiency' below.

The FDA approval of EMCITATE was supported by a comprehensive clinical development program evaluating EMCITATE in patients with MCT8 deficiency, including ReTRIACt, Triac Trial I, Triac Trial II, Erasmus Medical Center (EMC) Cohort Study, EMC Survival Study and the U.S. Expanded Access Program.

"*Today marks a turning point for patients living with MCT8 deficiency and their caregivers, who have waited long for an approved treatment in the United States. Our immediate focus is ensuring that eligible patients can access EMCITATE as quickly as possible,"* **said Nicklas Westerholm, Chief Executive Officer of Egetis Therapeutics.** *"We are deeply grateful to the patients, caregivers, investigators, clinicians, and advocacy organizations whose partnership and determination made this achievement possible as well as all Egetis employees and collaborators for their dedicated and hard work. Today also marks a defining milestone for Egetis as we take steps forward in developing medicines that address serious unmet medical needs for patients with rare diseases."*

"*Through my experience caring for patients with MCT8 deficiency, I have seen firsthand the profound impact this complex and life-limiting disorder can have on patients and their families. Early diagnosis is critical so that patients can be appropriately evaluated, connected with specialists and receive coordinated multidisciplinary care. The FDA approval of EMCITATE provides physicians in the United States with the first approved treatment option for patients and represents an important advance for the MCT8 deficiency community,"* **said Andrew J. Bauer, M.D.**, a pediatric endocrinologist and expert in thyroid hormone disorders and Principal Investigator in ReTRIACt trial and Triac Trial II, evaluating EMCITATE in MCT8 deficiency.

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"The FDA approval of EMCITATE is a historic milestone for the MCT8 deficiency community and an important step toward ensuring patients have access to a treatment. We are grateful to Egetis and to the researchers, clinicians, patients, families, and advocates whose dedication helped bring this treatment to patients. This approval is a testament to what is possible when a community comes together with a shared commitment to advancing care. We look forward to continuing to advocate for patients and supporting efforts to expand awareness, access and treatment options for the worldwide MCT8 community." **said the MCT8-AHDS Foundation**.

Launch of Egetis RareLink™: EMCITATE® comprehensive patient support program
Egetis is committed to helping eligible patients gain timely access to EMCITATE. The Company expects EMCITATE to be commercially available in the United States in eight to ten weeks post approval. Through **Egetis RareLink**, its dedicated patient support program, Egetis has established the access infrastructure—including specialty distribution and dedicated support resources—to help ensure a seamless experience for patients, caregivers, and healthcare professionals from day one. As part of its U.S. commercialization strategy, Egetis has partnered with PANTHERx® Rare to support medication access, education, care coordination and ongoing treatment services. For more information about Egetis RareLink, call 1-844-4EGETIS (1-844-434-3847).

Priority review voucher granted
In connection with the approval of EMCITATE, the FDA granted Egetis a Rare Pediatric Disease Priority Review Voucher (PRV). The Company currently expects to explore monetization of the PRV, which could potentially occur in the fourth quarter of 2026, subject to market conditions.

Conference call and webcast information
Egetis will host a conference call and webcast for analysts and investors to discuss the FDA approval of EMCITATE beginning at 8:00 am CEST (2:00 am EDT) on Tuesday September 29, 2026.
Webcast link: https://live.events.inderes.com/fda-approval-sep-2026
Teleconference link: https://events.inderes.com/live/fda-approval-sep-2026/dial-in

After registration to the teleconference you will be provided phone numbers and a conference ID to access the call. You can ask questions verbally via the teleconference. A replay of the webcast can be accessed via the webcast link above.

About MCT8 Deficiency

Monocarboxylate transporter 8 (MCT8) deficiency, also known as Allan–Herndon–Dudley syndrome (AHDS), is a rare, devastating, life-limiting, X-linked disorder caused by pathogenic mutations in the *SLC16A2* gene. These mutations impair the function of MCT8, a critical cell-surface thyroid hormone transporter responsible for thyroid hormone transport in specific cells, including in the brain. As a result, patients experience disrupted thyroid hormone signaling, characterized by insufficient thyroid hormone activity in the central nervous system and excessive exposure to the active thyroid hormone triiodothyronine (T3) in peripheral tissues. This leads to a complex disorder characterized by severe neurodevelopmental impairment and persistent peripheral thyrotoxicosis.

The elevated T3 concentrations in peripheral tissues can result in a chronic hypermetabolic state affecting multiple organs, including the heart, muscles, liver, and kidneys. Clinical manifestations may include failure to thrive, cardiovascular strain, muscle wasting, metabolic imbalance, and increased susceptibility to infections. These systemic consequences of persistent thyrotoxicosis are believed to contribute significantly to the increased morbidity and premature mortality associated with the disorder. Patients with MCT8 deficiency have a reported median life expectancy of approximately 35 years.

For more information about MCT8 deficiency, please visit MCT8deficiency.com or LifewithMCT8deficiency.com

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INDICATION AND USAGE

EMCITATE is a thyroid hormone receptor agonist indicated for the treatment of peripheral thyrotoxicosis in adults and pediatric patients with monocarboxylate transporter 8 (MCT8) deficiency (Allan–Herndon–Dudley syndrome).

Limitation of use: EMCITATE is not recommended for the treatment of primary hypothyroidism.

IMPORTANT SAFETY INFORMATION

BOXED WARNING
NOT FOR TREATMENT OF OBESITY OR FOR WEIGHT LOSS

CONTRAINDICATIONS
Primary hyperthyroidism

WARNINGS AND PRECAUTIONS
Thyrotoxicosis: Signs and symptoms of thyrotoxicosis (e.g., increased heart rate, elevated blood pressure, diarrhea, hyperhidrosis, irritability, insomnia, nightmares) have occurred with EMCITATE during treatment initiation and dose titration. Monitor and adjust the EMCITATE dose as indicated.
Laboratory Test Interference for T3 Measurement: Tiratricol can cross-react with immunoassays for T3 leading to unreliable T3 results and cause an overestimation of T3.

ADVERSE REACTIONS
Most common adverse reactions (≥ 5%): diarrhea, vomiting, rash, and hyperhidrosis.
To report SUSPECTED ADVERSE REACTIONS, contact Egetis Therapeutics US Inc. at 1-844-4EGETIS (1-844-434-3847) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information here:
https://www.egetis.com/wp-content/uploads/emcitate-full-prescribing-information.pdf

About Egetis Therapeutics

Egetis Therapeutics is a commercial-stage pharmaceutical company focused on developing and delivering innovative therapies for patients with rare diseases with significant unmet medical need. Combining scientific and clinical expertise with integrated late-stage development, regulatory and commercial capabilities and manufacturing expertise, Egetis is committed to delivering treatments and dedicated support to underserved patient communities.
The Company's lead product, EMCITATE® (tiratricol), is the first and only approved treatment for MCT8 deficiency, a rare and life-shortening genetic disorder, with marketing authorizations in the European Union and in the United States.
Headquartered in Stockholm, Sweden, with operations in the U.S. and Europe, Egetis is building a sustainable global rare disease company.
For more information, visit egetis.com and follow the Company on LinkedIn.

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About PANTHERx Rare

PANTHERx Rare makes rare disease care more hyper-personalized and less overwhelming by focusing relentlessly on each patient and each therapy. PANTHERx experts develop deep personal relationships with patients, prescribers, and pharmaceutical partners, serving as trusted advocates to ensure seamless collaboration and exceptional care. Since its founding in a garage in Pittsburgh, PA in 2011, PANTHERx has grown into the largest independent rare pharmacy in the U.S., leveraging established-company resources while maintaining small-company responsiveness, innovation, and attention to detail.
PANTHERx is licensed in all 50 states and U.S. territories and was the first national pharmacy to achieve dual accreditations in rare disease from the Accreditation Commission for Health Care (ACHC) and Utilization Review Accreditation Commission (URAC). PANTHERx is also the nine-time winner of the prestigious MMIT Patient Choice Award for patient satisfaction, including the 2026 honor.
For more information, please email TheRareSP@pantherxrare.com or visit www.pantherxrare.com

For further information, please contact:

Nicklas Westerholm, CEO
+46 (0) 733 542 062
nicklas.westerholm@egetis.com

Karl Hård, Head of Investor Relations, Communications & Business Development
+46 (0) 733 011 944
karl.hard@egetis.com

This information is information that Egetis Therapeutics is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2026-09-28 23:45 CEST.

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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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