PRESS RELEASE
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Egetis and Er-Kim Expand Partnership to Broaden Access to Emcitate® Across Central, Eastern, and Southeastern Europe

Stockholm, Sweden, December 10, 2025. Egetis Therapeutics AB (publ) ("Egetis" or the "Company") (NASDAQ Stockholm: EGTX), today announced that the Company, through its wholly-owned subsidiary Rare Thyroid Therapeutics International AB, has entered into an expanded exclusive distribution agreement with Er-Kim İlaç Sanayi ve Ticaret A.Ş. ("Er-Kim") to supply Emcitate® (tiratricol), for the treatment of MCT8 deficiency, across Albania, Bosnia & Herzegovina, Bulgaria, Croatia, Cyprus, Estonia, Greece, Hungary, Kosovo, Latvia, Lithuania, Montenegro, North Macedonia, Poland, Serbia and Slovenia. This follows an initial agreement signed in June 2025 covering Türkiye, marking another important milestone in the companies' growing collaboration.

Nicklas Westerholm, CEO of Egetis, commented: *"We are proud to extend our partnership with Er-Kim, whose strong local presence and deep expertise across these diverse markets make them an ideal partner to ensure that Emcitate® reaches patients in need as soon as possible. Our collaboration reflects a shared commitment to breaking down barriers to access and delivering innovative therapies to those with urgent, unmet medical needs—wherever they are.*

"We have launched Emcitate® in the first market, Germany, in May 2025, and aim to commercialize Emcitate® ourselves in the US and selected Western EU countries. In Japan, we have an exclusive license agreement for the development and commercialization of Emcitate® and in June 2025 we signed a distribution agreement with Er-Kim for Emcitate® in Türkiye. This was followed in October 2025 by a distribution agreement with another strategic partner for the Gulf Region. Building on our positive collaboration with Er-Kim, we have now expanded this partnership to include Central, Eastern and Southeastern Europe."

Cem Zorlular, CEO of Er-Kim, commented: *"We are pleased to expand our collaboration with Egetis, a company that shares our mission to deliver innovative medicines to more patients, faster. The unique tools and approaches we've built across the region exist for exactly this—bringing treatments like Emcitate® to patients across Türkiye, Central, Eastern, and Southeastern Europe."*

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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 has agreed with the FDA to submit a rolling NDA for Emcitate® (tiratricol), commencing in December 2025 targeting a complete NDA submission in early 2026 and anticipated completion of FDA's review process in the third quarter of 2026. 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

About Er-Kim

Established in 1981, Er-Kim stands at the forefront of biopharmaceutical innovation, partnering with over 40 global leaders to revolutionize patient care in key international markets. Our pioneering business models, tailored for sustainability and flexibility, have positioned us as a full-service solution, extending our reach to over 600 million patients through our fully-owned affiliates. With a dedicated team of over 300 professionals worldwide and revenues exceeding EUR 305 million, Er-Kim is not just a partner but a trailblazer in healthcare, continually setting new standards in commercialization and patient access. For more information, please visit http://www.er-kim.com/.

Attachments

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