

Egetis announces exclusive distribution agreement with Er-Kim for Emcitate® in Türkiye

Stockholm, Sweden, June 16, 2025. Egetis Therapeutics AB (publ) ("Egetis" or the "Company") (NASDAO Stockholm: EGTX), today announced that the Company, through its wholly-owned subsidiary Rare Thyroid Therapeutics International AB, has entered into an exclusive distribution agreement with Er-Kim İlaç Sanayi ve Ticaret A.Ş. ("Er-Kim") to supply Emcitate® (tiratricol), for the treatment of MCT8 deficiency, in Türkiye.

Nicklas Westerholm, CEO of Egetis, commented: "We are delighted to enter this partnership with Er-Kim, an ideal partner for expanding the access to Emcitate for MCT8 deficiency, with their strong track record of bringing new medicines to patients across emerging Europe, including Türkiye.

"We have launched Emcitate in the first market, Germany, on May 1, 2025, and aim to commercialize Emcitate ourselves in EU and the US. In Japan we have an exclusive license agreement for the development and commercialization of Emcitate with Fujimoto Pharmaceuticals. This is the first distribution agreement we have signed for Emcitate and we look forward to signing additional agreements in other regions."

Cem Zorlular, CEO of Er-Kim, commented: "We are delighted to collaborate with Egetis to expand access to this treatment for patients with MCT8 deficiency in Türkiye."

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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.

On February 13, 2025, the European Commission approved Emcitate® (tiratricol) as the first and only treatment for MCT8 deficiency in EU. Egetis launched Emcitate in the first country, Germany, on May 1, 2025.

The Company's lead drug candidate Emcitate® (tiratricol) is under development for the treatment of patients with monocarboxylate transporter 8 (MCT8) deficiency, a highly debilitating rare disease with no available treatment.

After a dialogue with the FDA, Egetis is conducting a randomized, placebo-controlled pivotal study in at least 16 evaluable patients to verify the results on T3 levels seen in previous clinical trials and publications. As previously communicated, the Company will update the market as soon as recruitment closes, and at that time, the Company will also provide information on when to expect topline results and when the Company plans to submit the NDA application in 2025.

Tiratricol holds Orphan Drug Designation (ODD) for MCT8 deficiency and resistance to thyroid hormone type 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 Rare Pediatric Disease Designation (RPDD) which gives Egetis the opportunity to receive a Priority Review Voucher (PRV) in the US, after approval. This voucher can be transferred or sold to another sponsor.

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 calmangafodipir has been parked until Emcitate marketing authorization submissions for MCT8 deficiency have been completed in the EU and the USA. Aladote has been granted ODD in the US and in the EU.

Egetis Therapeutics (Nasdaq Stockholm: EGTX) is listed on the Nasdaq Stockholm main market. 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 https://www.er-kim.com/.

Attachments

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