PRESS RELEASE
10 November 2023 08:37:00 CET

Egetis announces exclusive license agreement with Fujimoto to develop and commercialize Emcitate in Japan

Stockholm, Sweden, November 10, 2023. 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 exclusive license agreement with Fujimoto Pharmaceutical Corporation ("**Fujimoto**") to develop and commercialize *Emcitate* (tiratricol), for the treatment of MCT8 deficiency, in Japan. Under the terms of the agreement Egetis grants Fujimoto exclusive development and commercialization rights to *Emcitate* for the treatment of MCT8 deficiency in Japan. Fujimoto will pay upfront, development, and regulatory milestones amounting to JPY 600 million (approximately SEK 45 million). Egetis will supply Fujimoto with product in semi-finished form and will receive approximately one third of the applicable income from Fujimoto. Fujimoto will also finance the development program needed for *Emcitate* in Japan, which will be clarified after discussions with the Pharmaceuticals and Medical Devices Agency (PMDA). As a future marketing authorisation holder (MAH) Fujimoto will be responsible for regulatory interactions with the PMDA.

As previously communicated, Egetis intends to commercialize *Emcitate* through its own organization in the US and Europe, and seek partnerships in other markets. This is the first such partnership to be announced, driven by the anticipated need for a local clinical trial in Japan prior to regulatory submissions. In addition to the ongoing clinical trials with *Emcitate*, around 190 patients in over 25 countries around the world, are already being treated with *Emcitate* as part of Egetis' Managed Access programs. Furthermore, there is also a significant unmet medical need for treating MCT8 deficency patients in Japan. However, despite a significant number of patients diagnosed in Japan, none of these patients are currently treated with *Emcitate*. Iwayama et al. (Ref. 1) have reviewed the literature of MCT8 deficiency in Japan, and identified 36 already published cases. Kubota et al. (Ref. 2) in turn have conducted a nationwide survey of MCT8 deficiency and estimated there are over 60 cases with the disease in Japan, although this survey mainly asked questions to pediatric hospital facilities and did not survey adult departments.

Nicklas Westerholm, CEO of Egetis, commented: *"We are delighted to enter this partnership with Fujimoto, to bring a treatment for MCT8 deficiency to patients in Japan, where there is a significant unmet medical need. Fujimoto is an ideal partner for the development, regulatory process and commercialization of Emcitate in Japan, with their long track record of bringing new medicines to patients in Japan."*

Mr. Masaya Fujimoto, President of Fujimoto, commented: *"We have a long track record of bringing therapeutic medicines for CNS diseases, Blood diseases, and Orphan diseases to patients in Japan. We are pleased to have been granted the exclusive development and commercialization rights of Emcitate, an investigational drug candidate for MCT8 deficiency, from Egetis. Leveraging our previous experiences, we will continue to collaborate with Egetis and work diligently to obtain a marketing approval so that Emcitate can be used for the patients in Japan, as soon as possible."*

On October 9, 2023, the Company announced that it has submitted a marketing authorisation application for *Emcitate* for treatment of MCT8 deficiency to the European Medicines Agency (EMA). *Emcitate* has been granted Orphan Drug Designation by the EMA for MCT8 deficiency, and will, if approved by the European Commission be eligible for 10 years of market exclusivity within the EU.

As agreed with the US FDA, Egetis is conducting a randomized, placebo-controlled pivotal study (ReTRIACt) in 16 evaluable patients to verify the results on thyroid hormone T3 levels seen in previous clinical trials and publications. The study started recruiting in July this year. Topline results are expected during the first half of 2024 and Egetis intends to initiate the rolling

submission of a new drug application (NDA) in the US for *Emcitate* in mid-2024 under the Fast-Track Designation granted by FDA.

References:
1. Iwayama, H. et al (2021) Regional Difference in Myelination in Monocarboxylate Transporter 8 Deficiency: Case Reports and Literature Review of Cases in Japan. *Front. Neurol*. 12:657820. doi.org/10.3389/fneur.2021.657820
2. Kubota, M. et al. (2022) A nationwide survey of monocarboxylate transporter 8 deficiency in Japan: Its incidence, clinical course, MRI and laboratory findings. *Brain Development* 44:699-705. doi.org/10.1016/j.braindev.2022.07.007

Link to www.clinicaltrials.com:
ReTRIACt

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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* is under development for the treatment of patients with monocarboxylate transporter 8 (MCT8) deficiency, a highly debilitating rare disease with no available treatment. In previous studies (Triac Trial I and a long-term real-life study) *Emcitate* has shown highly significant and clinically relevant results on serum thyroid hormone T3 levels and secondary clinical endpoints. Egetis submitted a marketing authorisation application (MAA) for *Emcitate* to the European Medicines Agency (EMA) in October 2023.
After a dialogue with the FDA, Egetis is conducting a small randomized, placebo-controlled pivotal study in 16 patients to verify the results on T3 levels seen in previous clinical trials and publications. Egetis intends to submit a new drug application (NDA) in the US for *Emcitate* in mid 2024 under the Fast-Track Designation granted by FDA.
Emcitate 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. *Emcitate* 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* 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 and the design of the upcoming pivotal Phase IIb/III study with the purpose of applying for market approval in the US and Europe for *Aladote* has been finalized after completed interactions with FDA, EMA and MHRA and study start is planned after *Emcitate* submissions have been completed. *Aladote* has been granted ODD in the US and in the EU.
Egetis Therapeutics (STO: EGTX) is listed on the Nasdaq Stockholm main market. For more information, see www.egetis.com

Attachments

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