PRESS RELEASE
10 August 2022 08:00:00 CEST

Egetis establishes subsidiary in the United States

Stockholm, Sweden, August 10, 2022. Egetis Therapeutics AB (publ) (Nasdaq Stockholm: EGTX) today announced that it has established a wholly-owned subsidiary in the United States, Egetis Therapeutics US Inc., incorporated in the state of Delaware.

The United States is a key market for patients suffering from MCT8 deficiency. Through the establishment of Egetis Therapeutics US Inc. the Company will continue the stepwise build-up of a commercial infrastructure in the US for the launch of Egetis lead drug candidate *Emcitate*. In the US, the Company is on track to submit an NDA for *Emcitate* in mid-2023 under the Fast-Track Designation granted by the FDA, after conducting a small randomized, placebo-controlled study in 16 patients to verify the results on thyroid hormone T3 levels seen in previous clinical trials and publications.

As previously announced, Sara Melton was appointed as President of North America at Egetis.

Nicklas Westerholm, CEO and President, Egetis Therapeutics AB, commented: "*I am delighted we have managed to establish a US subsidiary in a very short time frame. We are looking forward to building a small and effective team to allow us to bring Emcitate, after approval, to the MCT8-deficiency patients who urgently need new treatment options*."

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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 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 T3 levels and secondary clinical endpoints. As a result of fruitful regulatory interaction Egetis intends to submit a marketing authorisation application (MAA) for *Emcitate* to the European Medicines Agency (EMA) in the first half of 2023 based on existing clinical data.
In the US, after discussions with the FDA, Egetis will conduct a small randomized, placebo-controlled 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-2023 under the Fast-Track Designation granted by FDA.
Emcitate is currently being investigated in the fully recruited Triac Trial II, a Phase II/III study in very young MCT8 deficiency patients (<30 months of age) exploring potential disease modifying effects of early intervention from a neurocognitive and neurodevelopmental perspective. Results are expected in the first quarter of 2024 and are expected to be submitted post-approval to regulatory authorities shortly thereafter.
Emcitate holds Orphan Drug Designation (ODD) for MCT8 deficiency and resistance to thyroid hormone type beta (RTH- #) in the US and the EU. *Emcitate* has been granted Rare Pediatric Disease Designation (RPD) which gives Egetis the opportunity to receive a Priority Review Voucher (PRV) in the US, after approval.
The drug candidate *Aladote* is a first in class drug candidate developed to reduce the risk of acute liver injury associated with paracetamol (acetaminophen) poisoning. 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. *Aladote* has been granted ODD in the US and has received a positive opinion for ODD 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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