PRESS RELEASE
Egetis Therapeutics AB
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Egetis Therapeutics receives FDA Fast Track Designation for Emcitate® for MCT8 deficiency

Egetis Therapeutics AB (publ) (ticker: EGTX) today announced that the U.S. Food and Drug Administration (FDA) has granted the company's lead candidate drug Emcitate®, currently in a pivotal study, Fast Track Designation for the treatment of the rare genetic disease MCT8 deficiency.

The FDA's Fast Track process is designed to facilitate the development and expedite the review of new drugs intended to treat serious or life-threatening conditions to address an unmet medical need with the purpose of getting important new drugs to the patient earlier. Fast Track designation provides a company early and more frequent communication with the FDA to improve the efficiency of the investigational drug's development and provides eligibility for priority review if certain criteria are met.

"This Fast Track Designation is an acknowledgement from the FDA of the importance of Emcitate to address the significant unmet medical need in MCT8 deficiency and ultimately help these patients that suffer from this rare and devastating disease. These patients are currently left without any treatment options. With a Fast Track designation come opportunities to expedite both the NDA submission and FDA's review which can enable Emcitate's regulatory approval sooner" said Nicklas Westerholm, CEO of Egetis Therapeutics.

A first clinical trial in patients suffering from MCT8 deficiency of all ages has been concluded with significant and clinically relevant results. A pivotal clinical trial looking at early intervention in very young MCT8 deficient children is under way. Recruitment is expected to be completed in Q4 2021. Emcitate has been granted Orphan Drug Designation in the US and EU. Emcitate was also granted US Rare Pediatric Disease Designation in November 2020, eligible to apply for a Priority Review Voucher.

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About Egetis Therapeutics

Egetis Therapeutics is an innovative, unique, and integrated pharmaceutical drug development company, focusing on projects in late-stage development for treatment of serious rare/niche diseases with significant unmet medical needs in the orphan drug segment. The drug candidate Emcitate is developed as the first potential treatment for patients with MCT8 deficiency, a rare disease with high unmet medical need and no available treatment. A Phase IIb clinical trial has been completed with significant and clinically relevant effects. A pivotal Phase IIb/III early intervention study has been initiated with the first patient dosed in Dec 2020 and interim results are expected in 2022. Emcitate holds Orphan Drug Designation (ODD) in the US and EU and was granted Rare Pediatric Disease Designation by the US FDA in November 2020. The drug candidate Aladote is a first in class drug candidate developed to reduce the risk of acute liver injury associated with paracetamol poisoning. A proof of principle study has been successfully completed and the design of the upcoming pivotal Phase IIb/III study for Aladote has been finalized after completed interactions with FDA, EMA and MHRA. Aladote

has been granted Orphan Drug Designation in the US and an application for ODD was submitted in Europe in Q1 2021.

Egetis Therapeutics (STO: EGTX) is listed on the Nasdaq Stockholm main market. For more information, see http:// www.egetis.com/

About MCT8 Deficiency

MCT8 deficiency is a rare genetic disease with high unmet medical need and no available treatment, affecting 1:70,000 males. Thyroid hormone is crucial for the development and metabolic state of virtually all tissues. Thyroid hormone transport across the plasma membrane is required for the hormone's metabolism and intracellular action and is facilitated by thyroid hormone transporters, including monocarboxylate transporter 8 (MCT8). Mutations in the gene for MCT8, located at the X-chromosome, cause MCT8 deficiency, also called Allan-Herndon-Dudley syndrome (AHDS) in affected males. The resulting dysfunction of MCT8 leads to impaired transport of thyroid hormone into certain cells and across the blood-brain-barrier and disruption of normal thyroid hormone regulation. This leads to a complex pattern of symptoms with neurological developmental delay and intellectual disability, accompanied by severely elevated circulating thyroid hormone concentrations which are toxic for tissues including the heart, muscle, liver and kidney and results in symptoms such as failure to thrive, cardiovascular stress, insomnia and muscle wasting. Most patients will never develop the ability to walk or even sit independently. At present there is no approved therapy available for the treatment of MCT8 deficiency.