PRESS RELEASE
31 May 2022 15:30:00 CEST

Change in the number of shares and votes in Egetis Therapeutics

Stockholm, Sweden, May 31, 2022. The number of shares and votes in Egetis Therapeutics AB (publ) ("Egetis" or the "Company") (STO: EGTX) has increased in the month of May as a result of the guaranteed issue of shares with preferential rights (the "Rights Issue").
As a result of the Rights Issue the total number of shares and votes has increased by 49 520 568, to 214 589 128. The share capital has increased by SEK 2 606 347, to SEK 11 294 169.
The shares in the Rights Issue will be registered with the Swedish Companies Registration Office in June 2022.

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This information is information that Egetis Therapeutics is obliged to make public pursuant to the Financial Instruments Trading Act. The information was submitted for publication at 2022-05-31 15:30 CEST.

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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 an application for ODD was submitted in the EU in the first quarter of 2021. There is an ongoing dialogue with EMA on the appropriate scope of the indication for an 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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