PRESS RELEASE
16 December 2024 17:20:00 CET

Issuance and repurchase of class C shares for incentive programs

Stockholm, Sweden, December 16, 2024. The Board of Directors for Egetis Therapeutics AB (publ) (Nasdaq Stockholm: EGTX) has resolved to issue a total of 29,000,000 new class C shares and to immediately thereafter repurchase such 29,000,000 issued class C shares, for the purpose of the outstanding long-term incentive programs ESOP 2021, ESOP 2022, ESOP 2023 and ESOP 2024. The resolution by the Board of Directors was passed based on the authorizations granted by the annual general meeting held on May 6, 2024.

Svenska Handelsbanken AB (publ) will subscribe for all issued class C shares at a subscription price of approximately SEK 0.052632 per share, equal to the quota value of the shares. All 29,000,000 issued class C shares will be repurchased by Egetis Therapeutics AB (publ) for the same price per share. Following the share issuances, the share capital will increase by approximately SEK 1,526,316.36. The class C shares do not entitle to dividends and each share entitles to 1/10 voting right.

The purpose of the issuances and repurchase is to ensure future delivery of shares to participants in, as well as to cover any costs for social contributions arising as a result of, ESOP 2021, ESOP 2022, ESOP 2023 and ESOP 2024. The class C shares will be reclassified to ordinary shares before delivery to the participants in the programs.

Egetis Therapeutics AB (publ) will, following the issuances and repurchase of the 29,000,000 class C shares, hold all class C shares in the Company.

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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 tiratricol (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) tiratricol has shown highly significant and clinically relevant results on serum thyroid hormone T3 concentrations and secondary clinical endpoints. In June 2024, topline results were presented from the Phase 2 study, Triac Trial II, with tiratricol for the treatment of MCT8 deficiency. The study investigated a potential additional treatment effect on neurocognitive development in young children under 30 months with MCT8 deficiency. The study did not show a statistically significant improvement compared to historical controls.

On December 12, 2024, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion for Emcitate® (tiratricol) for the treatment of MCT8 deficiency.

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.

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 calmangafodipir (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. 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 tiratricol marketing authorization submissions for MCT8 deficiency have been completed in the EU and the USA. Calmangafodipir 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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