

Flerie's portfolio company Egetis Therapeutics ready for NDA after positive results from the ReTRIACt study with Emcitate®

Flerie AB's (publ) portfolio company Egetis Therapeutics has announced positive data from its ReTRIACt study. The results strengthen and complement the company's prior clinical data for Emcitate® (tiratricol) in treating patients with MCT8 deficiency, a rare genetic disease. Following discussions with the FDA at a pre-NDA meeting in October 2025, Egetis now has all the required documentation to submit a New Drug Application (NDA) in the US.

Egetis plans to initiate a rolling NDA submission in the near term, aiming to complete it in early 2026. The FDA review process is anticipated to conclude in the third quarter of 2026, subject to the granting of Priority Review.

"We are very encouraged by Egetis' progress with Emcitate and the positive results from the ReTRIACt study. The completion of a comprehensive dossier for NDA submission, combined with the FDA process advancing as planned, reinforces our confidence in Egetis' capacity to address a critical unmet medical need in patients with MCT8 deficiency and the company's potential to deliver substantial value to both patients and shareholders," says Ted Fjällman, CEO of Flerie.

Read Egetis Therapeutics' full press release here: https://www.egetis.com/mfn_news/egetis-announces-positive-results-from-the-retriact-study-of-emcitate-tiratricol-in-mct8-deficiency/

Flerie's holding in Egetis Therapeutics amounts to 1%.

For more information:

Ted Fjällman, CEO

Email: ir@flerie.com

Flerie in brief

Flerie is an active long-term life science investor, with a broad and diversified portfolio of innovative companies based on pioneering science. We invest in product development and commercial growth opportunities globally alongside other leading investors, focusing predominantly on private companies that are otherwise difficult to access. Flerie's active ownership model, broad network and resources support and accelerate the development of the portfolio projects, creating value for shareholders. Flerie AB's ordinary share is listed on Nasdaq Stockholm with the ticker FLERIE. For further information please visit www.flerie.com

Attachments

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