Flerie's portfolio company Egetis Therapeutics receives US approval for its drug EMCITATE®

Flerie AB's (publ) portfolio company Egetis Therapeutics has received approval from the US Food and Drug Administration (FDA) for EMCITATE® (tiratricol). The drug is expected to become available in the US within 8 to 10 weeks. The approval covers the treatment of peripheral thyrotoxicosis in adult and paediatric patients with MCT8 deficiency (Allan–Herndon–Dudley syndrome).

EMCITATE® is the first and only FDA-approved treatment for patients with MCT8 deficiency, a rare, severe and life-limiting X-linked disorder that primarily affects boys. In connection with the approval, the FDA also granted Egetis a Rare Pediatric Disease Priority Review Voucher (PRV), which the company intends to evaluate for divestiture, potentially in the fourth quarter of 2026.

Egetis expects EMCITATE® to become commercially available in the US within eight to ten weeks and has launched a patient support program in collaboration with PANTHERx® Rare, the largest independent specialty pharmacy for rare diseases in the US.

"The approval of Emcitate is a milestone for patients with MCT8 deficiency and their families, who until now have lacked an approved treatment option in the US. It is also a clear example of the value of providing long-term support to companies developing drugs for rare diseases with significant medical needs. We congratulate Egetis on this remarkable achievement," says Ted Fjällman, CEO of Flerie.

Read Egetis Therapeutics' full press release here: https://www.egetis.com/news/egetis-therapeutics-announces-u-s-fda-approval-of-emcitate-tiratricol-for-patients-with-mct8-deficiency/

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

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About MCT8 deficiency
MCT8 deficiency is a rare genetic disease that primarily affects boys and men. The condition is caused by a defective gene that contains the instructions for producing the transport protein MCT8, a crucial protein responsible for transporting thyroid hormone into the brain. Because thyroid hormone cannot cross the blood-brain barrier without the MCT8 transporter, the brain receives too little of the hormone, while excessively high levels accumulate in the blood. Many patients with MCT8 deficiency suffer a range of severe consequences, including an inability to walk or sit without support, absent or severely limited speech, intellectual disability, feeding difficulties, and chronic cardiac and metabolic strain.

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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