

## Egetis continues to strengthen the commercial and medical affairs organizations for the expected launch of Emcitate® in 2024

**Stockholm, Sweden, November 18, 2022.** Egetis Therapeutics AB (publ) (NASDAQ Stockholm: EGTX) today announced further key recruitments to its commercial and medical affairs organizations in the United States and Europe, in preparation for the expected launch of Egetis lead drug candidate *Emcitate* in 2024. These key recruitments bring substantial experience and proven track records in successful launch preparations and commercialization of drugs in ultra-orphan diseases, including Spinraza®, Brineura® and Tecfidera®.

**Nigel Nicholls** will take on the position as General Manager (GM) UK and Northern European Cluster (Ireland, Nordics and Baltics). He will join Egetis in April 2023 and be based in the UK.

**Raymond Francot** will take on the position as GM Germany, Austria, Switzerland and Central and Eastern European Cluster. He will join Egetis in January 2023 and be based in Zurich, Switzerland and Munich, Germany.

**Sylvain Forget** will take on the position as GM France and Southern European Cluster (Portugal, Spain, Italy and Greece). He will join Egetis in January 2023 and be based in Paris, France.

**John Walsh** has been recruited as Vice President of Medical Affairs, North America. He joined Egetis in October 2022 and is based in Cape Coral, Florida, USA.

**Kate Sulham** has been recruited as Vice President of Market Access and Pricing, North America. She joined Egetis in October 2022 and is based in Boston, Massachusetts, USA.

**Nicklas Westerholm, CEO of Egetis, said:** *"We continue to stepwise establish inhouse commercial capabilities with the aim of having an organization of 40-50 employees, in the USA and Europe combined, at time of launch of Emcitate in 2024. It's a pleasure to welcome these highly experienced professionals to Egetis. I'm honored to see that we can recruit top talent, with experience from some of the most successful biotech companies, and with proven track records of launching drugs in ultra-orphan diseases."*

**Nigel Nicholls** joins from Global Blood Therapeutics (GBT). Prior to GBT, Nigel spent over 10 years at BioMarin as area director and country manager for UK & Ireland. At BioMarin he managed the introductions of NICE managed access agreements for Vimizim® (elosulfase alfa) for Morquio A syndrome and for Brineura® (cerliponase alfa) for ceroid lipofuscinosis 2 (CLN2).

**Raymond Francot** joins from Myriad Genetics where he has held roles as Chief Commercial Officer Europe and Executive Vice President, Head of International Operations. Between 2011-2017 Raymond was General Manager Germany, Austria, Switzerland and Central and Eastern Europe at Vertex Pharmaceuticals and launched several orphan drugs for cystic fibrosis.

**Sylvain Forget** joins from a role as CEO at BlueDil International Ltd. Between 2006-2013 Sylvain was Vice President Europe Middle East North Africa (EMENA) at SOBI. The EMENA region covered 27 countries and commercialized 17 products dedicated to rare diseases. Earlier in his career Sylvain worked at NovoNordisk, Lundbeck, Zambon and Glaxo.

**John Walsh** joins from Thirteen Consulting Group, where he was a Medical Affairs consultant. Between 2017-2020 John was Vice

President, North America Medical Affairs at EMD Serono. Prior to that he was at Biogen, in several leadership roles, including the launches of Spinraza® (nusinersen) for spinal muscular atrophy and Tecfidera® (dimethyl fumarate) for multiple sclerosis.

**Kate Sulham**, consulted for multiple early-stage biopharmaceutical companies focusing on market access and value-based reimbursement strategies, prior to joining Egetis. She previously held leadership roles at Spero Therapeutics and The Medicines Company, leading Medical Affairs and Global Value & Access, respectively. Kate has also held several consulting roles at GfK, PatientsLikeMe, Boston Healthcare Associates, and Mapi Values.

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**About Egetis Therapeutics**

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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 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. The recruitment target was achieved in the second quarter 2022 and 22 patients have been included in the study. Results are expected mid 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-beta) in the US and the EU. MCT8 deficiency and RTH-beta are two distinct indications, with no overlap in patient populations. *Emcitate* 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.

The drug candidate *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 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 and study start is planned for early 2023. *Aladote* 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](http://www.egetis.com)

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**PRESS RELEASE**

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## **Attachments**

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[Egetis continues to strengthen the commercial and medical affairs organizations for the expected launch of Emcitate® in 2024](#)