Umecrine Cognition resumes patient inclusion in its clinical Phase I/IIa study of golexanolone in primary biliary cholangitis

STOCKHOLM – May 26, 2025. Umecrine Cognition today announces that the company has informed its clinical partners and study center investigators that they may resume the inclusion of eligible primary biliary cholangitis (PBC) patients to the Phase I/IIa study evaluating the treatment safety and efficacy of golexanone. This will occur step-wise across study sites, due to differences in regional regulatory requirements. The study was halted by the company in February following a temporary manufacturing issue concerning the packaging of the study drug. As previously announced, the issue had no impact on patient safety and has now been resolved.

Umecrine Cognition is developing golexanolone, a clinical-stage drug candidate targeting impaired cognitive function and central fatigue in Primary Biliary Cholangitis. Golexanolone is currently being evaluated in a two-part Phase 1b/2a clinical study. The ongoing second part of the clinical study (part B) aims to further document the pharmacological profile of golexanolone, as well as evaluate the treatment's efficacy on cognitive symptoms and fatigue in PBC patients.
"We are glad to announce that the clinical Phase I/IIa study of golexanolone is again including new patients. During the hiatus, we have had many positive interactions with clinicians engaged in the study, who report that they have used the time to prepare for the re-initiation of new patient screenings. This gives confidence that the restart will have a high acceleration up to the previous study pace," says Dr. Viktor Drvota, CEO of Umecrine Cognition.

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About Umecrine Cognition
Umecrine Cognition AB is developing a completely new class of drugs for the treatment of symptoms in the central nervous system related to chronic neuroinflammation – a devastating brain distortion that can lead to severely impaired cognition and fatigue. Chronic neuroinflammation can occur as a result of a number of underlying conditions, including a range of liver diseases as well as neurodegenerative diseases, such as Parkinson's disease. Results from an internationally acclaimed Phase 2 clinical study indicate that the company's most advanced drug candidate, the GABAA receptor-modulating steroid antagonist golexanolone, normalizes brain signaling and improves cognition and alertness in patients with hepatic encephalopathy. A Phase 2 study is currently ongoing in patients with primary biliary cholangitis. Further, based on intriguing preclinical data, the company is considering pursuing the development of golexanolone in patients with Parkinson's disease. For more information, visit www.umecrinecognition.com

Attachments

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