Umecrine Cognition reports last patient out in Phase 1b/2a study evaluating golexanolone in primary biliary cholangitis

STOCKHOLM – September 15, 2026. Umecrine Cognition today announced that the last patient has completed the final follow-up visit in the company's Phase 1b/2a study of golexanolone in patients with primary biliary cholangitis (PBC). The study evaluates the effect of golexanolone on fatigue and cognitive symptoms. Results are expected early November, 2026.

The randomized, double-blind, placebo-controlled study consists of two parts and was carried out in over 30 sites in eight European countries. Part A investigated the safety and pharmacokinetics in eight patients who received golexanolone 40 mg or placebo twice daily for five days. In part B, 99 patients received golexanolone 40 mg, 80 mg or placebo twice daily for 28 days. The last patient visit was performed as planned and concluded the full study. The study has now entered the last data review phase, in which all clinical data are collected, verified and prepared ahead of database lock, after which the data will be unblinded and analysed by independent third-party statisticians.

"Last patient out is an important milestone for the study and for Umecrine Cognition, and it reflects the collective effort of investigators, site teams and our internal study team. We are now working intensively on the final data processing ahead of the study readout. We are deeply grateful to the patients who took part, and to everyone whose expertise and commitment have carried the study to this point." says Pernilla Sandwall, COO of Umecrine Cognition.

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About the Phase 1b/2a study UCAB-CT-05
UCAB-CT-05 is a randomized, double-blind, placebo-controlled, two-part Phase 1b/2a study designed to evaluate the safety, pharmacokinetics, and preliminary efficacy of golexanolone in patients with primary biliary cholangitis (PBC) who experience clinically significant fatigue and cognitive symptoms. Part A (5 days, 40 mg twice daily) assessed safety and pharmacokinetics, while Part B (28 days, 40 mg or 80 mg twice daily) is evaluating efficacy using validated patient-reported and clinical measures. Key efficacy assessments include changes from baseline in the PBC-40 domains (cognition, fatigue, itch, social, emotional, and general symptoms), EQ-5D-3L, Epworth Sleepiness Scale, a cognitive test battery (PHES, RAVLT, D-KEFS), and the Clinical Global Impression of Change specific for PBC (CGI-C-PBCTM). The study is conducted across more than 30 sites in Europe and Turkey.

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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