Umecrine Cognition enrolls last patient in its ongoing Phase 1b/2a study of golexanolone

STOCKHOLM – August 3, 2026. Umecrine Cognition today announced that the last subject has been enrolled in the company's ongoing Phase 1b/2a clinical study evaluating the safety, pharmacokinetics, and preliminary efficacy of golexanolone in patients with primary biliary cholangitis (PBC). The phase 2a part enrolled 99 patients in total and expects to present results in the second half of 2026.

In June, the company announced that it had completed an interim sample size analysis in its clinical study, concluding that patient recruitment could continue as previously planned. The last patient has now been enrolled in the study and will complete the treatment period within the upcoming quarter. The study is 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.

"We are very excited to see the last patient being enrolled in the study. The high inflow of eligible individuals speaks to the stark reality of the symptoms that ail this patient group, and the demand for meaningful complementary treatments that manage central fatigue and reversible cognitive dysfunction," comments Professor David E. Jones, Coordinating Principal Investigator and Professor of Liver Immunology at Newcastle University

Patient recruitment has accelerated over the course of the study, reflected by key insights from the study's management and an increased awareness of the range of impactful symptoms in PBC. The study is conducted across more than 30 clinics in Europe and Turkey. In total, the second part of the study enrolled 99 patients and the top-recruiting clinic is led by Professor Trivedi at the University of Birmingham, UK, and his team with registered nurse Gifty Riverson as instrumental to the success. The results are expected in the second half of 2026.

"Over the course of the study, we have gathered valuable insights from both the medical and scientific community, as well as the patient community, that have been important for the company beyond completing the study. We look forward to presenting our full study data later this year and remain hopeful for golexanolone's outlook to improve symptom management in PBC patients," says Dr. Magnus Doverskog, SVP & Chief Scientific Officer, Umecrine Cognition.

For further information, please contact:

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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-PBC™). 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 a previously completed 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, and results are expected during the second half of 2026. 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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