Umecrine Cognition will present patient survey data at EASL 2026 suggesting golexanolone addresses critical unmet need in PBC

STOCKHOLM – May 13, 2026. Umecrine Cognition today announced new data from the UK-PBC national cohort, to be presented at the EASL Congress 2026 in Barcelona. The data show that most patients with primary biliary cholangitis (PBC) who experience clinically significant fatigue or cognitive symptoms do not have clinically significant itch, challenging a previously prevailing paradigm. The findings support the need for therapies that specifically address the central nervous system (CNS) symptoms of PBC, alongside recent advances in itch-directed treatment.

The analysis, based on PBC-40 symptom assessment tool responses from 1,964 well-characterized patients in the UK-PBC cross-sectional national cohort, found that 57% of patients experienced clinically significant fatigue and 36% reported fatigue with clinically significant cognitive symptoms. Critically, of those with fatigue, 54% did not have significant itch, and of those with cognitive symptoms, 52% did not have itch. The contribution of itch to fatigue appeared to be lowest in the group with "central" fatigue; the form of fatigue with the greatest impact on daily living. While recent advances – including iBAT inhibitors such as linerixibat, as well as fibrates and PPAR agonists – represent important progress for patients with cholestatic pruritus, the new data demonstrate that itch-directed therapy cannot be expected to resolve fatigue or cognitive dysfunction in the majority of affected patients. The findings reinforce the need for dedicated, purpose-built CNS therapies as a complementary pillar in a more individualized symptom franchise for PBC. Umecrine Cognition is developing golexanolone, currently in a Phase 1b/2a study (UCAB-CT-05) in PBC patients with clinically significant fatigue and cognitive symptoms.

"These real-world data from nearly 2,000 UK patients make it clear that the quality-of-life burden in PBC cannot be explained by itch alone. Recent progress in cholestatic pruritus is welcome news for patients who suffer from severe itch, but more than half of patients with fatigue and cognitive symptoms will not be reached by those therapies. A dedicated CNS-targeted therapy, such as golexanolone, is needed to complete the PBC symptom franchise and deliver truly personalized care for every patient," comments Dr. Viktor Drvota, CEO of Umecrine Cognition.

The abstract (REG26-2685) "The majority of fatigued primary biliary cholangitis patients do not have clinically significant itch" will be presented by Professor David E. Jones, Newcastle University and Freeman Hospital, Newcastle, UK, at EASL 2026 in Barcelona on May 30 at the session "Immune-mediated and cholestatic disease: Clinical aspects".

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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). A pre-specified interim analysis supports adaptive sample-size re-estimation based on conditional power. The study, conducted across more than 30 European sites, continues to recruit participants following positive interim data from the first part of the study, presented at The Liver Meeting® 2024 (AASLD).

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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