Umecrine Cognition presents positive interim data from ongoing Phase 1b/2a study with golexanolone at the AASLD Liver Meeting in San Diego

STOCKHOLM – November 18, 2024. Umecrine Cognition today announces that the company will present late-breaking data from a recent interim analysis of the first part of its ongoing Phase 1b/2a clinical study of golexanolone in patients with Primary Biliary Cholangitis. The preliminary results show that golexanolone achieved drug exposure levels that correlate to clinical treatment doses and was well-tolerated as no serious adverse effects were observed. Professor David E. Jones, Principal Investigator, will present the company's data at the Late Breaking Poster session at the American Association for the Study of Liver Diseases' (AALSD) 75th Liver Meeting, on November 18, 2024.

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 results from an interim analysis, based on 8 patients in the first part of the study (part A), show that golexanolone (40 mg BID) is well-tolerated, as only mild adverse events were registered, and that the regimen achieved clinically relevant steady-state drug exposure levels after five days of treatment. Further, the study data registered positive outcomes in anxiety and depression scoring (HAD). 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 84 evaluable PBC patients. The interim study results will be presented by the Principal Investigator, Professor David E. Jones, at the Late Breaking Posters session on November 18.

"Currently approved treatments for Primary Biliary Cholangitis are effective in mitigating liver failure and impeding disease progression toward cirrhosis and fibrosis. However, these drugs lack a therapeutic effect on cognitive function and pathological fatigue – two symptom areas that have a substantial negative and debilitating impact on PBC patients' quality of life. Golexanolone is the first treatment in clinical development that targets CNS-mediated symptoms and that shows promise for the treatment of central fatigue in PBC. We are therefore encouraged by these interim results indicating safe and controlled dosing and reduced anxiety and depression scores on a group level," comments Dr. David Jones, Professor of Liver Immunology at Newcastle University, Honorary Consultant Hepatologist at Newcastle Hospitals NHS Foundation Trust, and Dean for NIHR Faculty Trainees.

In summary, the results show that golexanolone was well-tolerated by study patients at clinically relevant drug exposure levels, as indicated by findings in previous studies, and does not require dose adjustments. These findings suggest that golexanolone shows promise as a therapeutic for treating central fatigue in patients with PBC and potentially other disorders in the liver and the central nervous system.

"We are excited to share the results from our interim analysis of the ongoing clinical evaluation of golexanolone in primary biliary cholangitis. Data confirms the favorable safety profile of golexanolone and indicates a new treatment opportunity for patients with high unmet medical needs. There are currently no approved treatments available for these debilitating CNS-mediated symptoms. The second part of the Phase 1b/2a study is in progress at over thirty clinical research sites in eight European countries, and we look forward to presenting results H1 next year," says Anders Karlsson, Chief Executive Officer, Umecrine Cognition.

Read the abstract: no. 5028; Golexanolone does not require dose adjustment and is well tolerated by PBC patients with central fatigue at plasma levels shown to improve neuropsychiatric performance in CLD

Learn more about the conference: The American Association for the Study of Liver Diseases' 75th Liver Meeting.

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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 cirrhosis. 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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