Umecrine Cognition's Phase 1b/2 study of golexanolone in Primary Biliary Cholangitis progresses to Part B following positive safety review

STOCKHOLM – March 22, 2024. Umecrine Cognition today announces the successful completion of the first part (Part A) of its ongoing clinical Phase 1b/2 study in Primary Biliary Cholangitis. Part A interim data show that golexanolone exhibits a favorable safety and tolerability profile in the study population. The company's internal safety review committee (iSRC) has consequently authorized the initiation of Part B, which aims to evaluate the preliminary efficacy of golexanolone, and further study its safety and tolerability profile. Top-line results from Part B are expected in H1, 2025.

Umecrine Cognition is currently evaluating golexanolone in a randomized, double-blind, placebo-controlled, two-part phase 1b/2 study in patients diagnosed with non-cirrhotic or Child-Pugh class A cirrhotic primary biliary cholangitis (PBC) who display clinically significant fatigue and cognitive symptoms while on a stable background standard of care (SoC) PBC medication. In Part A, subjects have received orally administrated golexanolone (40 mg), or placebo, twice daily (BID) for five (5) days. The first part of the study aimed to evaluate the safety and tolerability profile, as well as the pharmacokinetic profile, of the drug candidate, and the data generated provide important guidance to the dosing intervals in Part B.

Following the successful outcome of the iSRC review, the company's board of directors has decided to initiate Part B shortly. Based on pharmacokinetic data from the first part of the study, Part B will continue without dose adjustments. In effect, approximately 84 evaluable subjects will be randomized (1:1:1) to bidaily (BID) administration of 40 mg or 80 mg golexanolone, or placebo, for twenty-eight (28) consecutive days. Apart from further evaluation of golexanolone's safety profile, the second part of the study aims to investigate preliminary treatment efficacy signals.

Part B of the Phase 1b/2 study will be conducted at 35 treatment centers, under the coordination of Professor David Jones, BM, BCh, FRCP, PhD, OBE, Professor of Liver Immunology, Newcastle University & Honorary Consultant Hepatologist, Newcastle upon Tyne Hospitals NHS Foundation Trust, United Kingdom.

"We are delighted by the successful outcome of the first part of our phase 1b/2 study of golexanolone in patients with primary biliary cirrhosis and are now looking forward to progressing the clinical program based on the intriguing data generated so far," said Anders Karlsson, CEO of Umecrine Cognition.

The first patient in Part B of the Phase 1b/2 study is expected to be included during the second quarter of 2024 and final results are slated for the middle of 2025. As part of the data evaluation, an interim analysis will also be performed for sample size re-assessment when three quarters of the patients completed day 28.

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About Umecrine Cognition AB
Umecrine Cognition AB develops a completely new class of pharmaceuticals against neurological disturbances in the brain that may arise as a consequence of several underlying diseases, leading to strongly reduced cognitive functions and wakefulness. Results from an internationally recognized clinical Phase 2 study indicates that the company's most advanced drug candidate, golexanolone, normalizes the brain's signaling and improves cognition as well as wakefulness in patients diagnosed with hepatic encephalopathy. The continued drug development will initially focus on patient groups whose symptoms arise from chronic liver diseases. The mode of action is however relevant in a number of other indications. For more information, visit www.umecrinecognition.com.

Attachments

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