Umecrine Cognition completes successful pre-IND meeting with FDA

STOCKHOLM – March 14, 2022. Umecrine Cognition AB today announces that the company has completed a pre-IND meeting with the U.S. Food and Drug Administration (FDA). Based on a recent interaction with the agency Umecrine Cognition has received formal feedback from the FDA. The input will play an important role in the planned clinical Phase 2 study of golexanolone in patients with cirrhosis and hepatic encephalopathy.

Umecrine Cognition is developing golexanolone, a novel GABAA receptor modulating steroid antagonist, which is currently in clinical development for cognitive dysfunction associated with neuroinflammation and chronic liver diseases including that experienced by patients with primary biliary cholangitis (PBC) and as well as hepatic encephalopathy (HE), which can occur in patients with clinically decompensated cirrhosis of any cause. Based on the drug candidate's novel mode of action and nonclinical findings, it shows potential for development for additional indications related to neuroinflammation [1].

The purpose of Umecrine Cognition's meeting with the FDA was twofold. Firstly, to obtain feedback from the FDA concerning chemistry, manufacturing, and controls (CMC) and non-clinical aspects of the company's planned clinical study in hepatic encephalopathy (HE). Secondly, the company sought feedback concerning clinical and regulatory aspects related to the study design and objectives, with regards to the potential of golexanolone as a treatment of HE in patients with liver cirrhosis and a history of overt hepatic encephalopathy (OHE).

The proposed Phase 2 study is a randomized, double-blind, parallel-arm, placebo-controlled investigation of golexanolone in patients diagnosed with hepatic encephalopathy. Treatment with the drug candidate will be compared against standard of care in patients with a history of OHE. The study will evaluate the effects of multiple dose levels on the occurrence of OHE events as well as features of covert HE (CHE). Cognitive function will be assessed using measures of neuropsychological and psychometric performance, as well as of sleepiness and sleep quality. Safety profile and the impact of treatment on health-related quality of life will also be assessed.

"The successful meeting and valuable input from FDA is an important milestone that will inform the design of our planned clinical Phase 2 study of golexanolone in patients with HE. Together with positive input from a recent successful scientific advisory meeting with the UK regulatory body, MHRA, we feel we are on the right track for the development of golexanolone, also in primary biliary cholangitis. Golexanolone has potential to revolutionize the treatment of patients with impairments in the brain, and we are now eager to move ahead in the clinical development of our unique drug candidate," said Magnus Doverskog, CEO of Umecrine Cognition.

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About Umecrine Cognition AB

Umecrine Cognition's golexanolone (aka GR3027) represents a first-in-class orally active product designed to normalize GABA-ergic transmission, of which allosteric activation by neurosteroids is implicated in several major CNS-related disorders, including HE, a potentially life-threatening disorder with high and growing unmet medical need, and cognitive dysfunction associated with PBC. Golexanolone was shown to inhibit allosteric activation by neurosteroids and normalize GABA-ergic transmission in humans. For more information, please visit www.umecrinecognition.com and see the references below.

[1] Company Press Release on February 21, 2022 (https://www.umecrinecognition.com/en/umecrine-cognition-to-present-preclinical-results-showing-beneficial-effects-of-golexanolone-on-neuroinflammation-and-movement-dysfunction/)

Attachments

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