Umecrine Cognition submits application for Phase 2 clinical trial of golexanolone

STOCKHOLM – May 19, 2022. Umecrine Cognition AB today announces that the company has submitted a clinical trial application (CTA) for a Phase 2 study of golexanolone in patients with primary biliary cholangitis, PBC. The clinical trial is planned to be performed at multiple medical centers in several European countries, and the first submission was made to the Hungarian regulatory body OGYÉI.

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 hepatic encephalopathy (HE), which can occur in patients with clinically decompensated cirrhosis of any cause, as well the cognitive dysfunction and fatigue that is a common and often disabling manifestation of primary biliary cholangitis (PBC). Based on the drug candidate's novel mode of action and an extensive preclinical data package [1], it shows potential for development in additional indications related to neuroinflammation.

The randomized, double-blind, placebo-controlled Phase 2 clinical trial will compare golexanolone to placebo in up to approximately 150 subjects with a non-cirrhotic or Child-Pugh class A cirrhotic primary biliary cholangitis (PBC) with clinically significant fatigue and cognitive symptoms on a stable background of standard of care (SoC) PBC medication.

The clinical trial will be performed stepwise in two parts: Part A will assess the pharmacokinetics (PK), safety, and tolerability of golexanolone in non-cirrhotic or Child-Pugh class A cirrhotic PBC subjects with clinically significant fatigue and cognitive symptoms. The aim of part B is to evaluate the safety and tolerability, and preliminary efficacy of golexanolone in the same patient population.

"The CTA submission for a Phase 2 study of golexanolone in patients with primary biliary cholangitis represents yet another key milestone in the development of our lead drug candidate as a novel treatment of a range of severe liver diseases with high unmet medical needs," said Magnus Doverskog, CEO of Umecrine Cognition.

The Phase 2 trial is expected to start in mid-2022, with a first safety and pharmacokinetic read-out at the end of the year, interim efficacy data in H2 2023, and final results slated for 2024.

For further information, please contact:
Magnus Doverskog, CEO, Umecrine Cognition AB
Phone: +46 (0) 73 039 20 52
e-mail: magnus.doverskog@umecrine.se

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 a 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

Umecrine Cognition submits application for Phase 2 clinical trial of golexanolone