

Umecrine Cognition secures funding ahead of Phase 2 study of golexanolone in patients with primary biliary cholangitis

STOCKHOLM – September 14, 2022. Umecrine Cognition today announces that the company has secured funding of SEK 41 million for the start of a Phase 2 study of its drug candidate golexanolone in primary biliary cholangitis, a condition that occurs when the bile ducts in the liver are slowly destroyed. The financing is being implemented as a convertible loan with attached share options, directed towards an investor consortium that includes Karolinska Development and AB Ility. The Phase 2 study aims to investigate the safety profile, pharmacokinetics, and preliminary efficacy of the drug candidate in the targeted patient population.

Umecrine Cognition is developing a new class of drugs to alleviate cognitive symptoms caused by liver disease. The company's most advanced drug candidate, golexanolone, is currently being evaluated in patients with primary biliary cholangitis (PBC) who also suffer from fatigue and cognitive impairment as well as in patients with clinically decompensated cirrhosis of all etiologies who suffer from hepatic encephalopathy (HE). These severe conditions lead to an inappropriate suppression of brain activity, causing extreme fatigue, cognitive impairment, difficulty concentrating, and impaired motor function. Results from previous clinical and pre-clinical studies strongly indicate that golexanolone can counteract such inappropriate suppression of brain activity and improve CNS symptoms.

"The strong interest from well-renowned and long-term investors to participate in Umecrine Cognition's financing round reflects the substantial commercial potential of our leading drug candidate, golexanolone. We are now looking forward to initiating the phase 2 study, an important milestone in our efforts to develop better treatments of cognitive symptoms caused by liver diseases," said Anders Karlsson, CEO of Umecrine Cognition.

Contact

Anders Karlsson, CEO, Umecrine Cognition AB
Phone: +46 70 918 00 10
E-mail: anders.karlsson@umecrine.se

About primary biliary cholangitis

Primary biliary cholangitis (PBC) is a chronic cholestatic orphan disease characterized by progressive destruction of the intra-hepatic bile ducts. This leads to impairment of bile flow and progressive cholestasis leading, ultimately, to biliary cirrhosis. Patients at all disease stages may experience significant cognitive symptoms. These symptoms are not a consequence of the related condition hepatic encephalopathy (HE), as most patients do not develop cirrhosis, and conventional HE is uncommon in PBC. Central fatigue is the most common symptom and affects about 60% of patients, of which approximately half experience a markedly reduced quality of life.

Standardized testing indicates that cognitive dysfunction, characterized by patients as "brain fog", including difficulty in concentrating and processing information and impaired short-term memory, is the next most common symptom. Fatigue and cognitive dysfunction also overlap in a significant subset of patients. The mechanism of non-cirrhotic cognitive dysfunction in PBC remains unknown. However, the elevation of neurosteroid levels has been reported by the company and is related to fatigue severity [1]. Effective treatment for central nervous system (CNS) symptoms in PBC is a key area of unmet clinical need in PBC [2].

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 November 3, 2021 (<https://www.umecrinecognition.com/en/umecrine-cognition-presents-data-supporting-a-new-predictive-biomarker-in-patients-with-primary-biliary-cholangitis-at-the-aasld-international-liver-meeting-2021/>)

[2] Phaw NA., Dyson JK., Mells G., Jones. D. Understanding fatigue in primary biliary cholangitis. Dig Dis Sci. 2021. PMID: 32851498

Attachments

[Umecrine Cognition secures funding ahead of Phase 2 study of golexanolone in patients with primary biliary cholangitis](#)