Umecrine Cognition secures additional funding to progress its drug development projects

STOCKHOLM – March 28, 2023. Umecrine Cognition today announces that the company has secured additional funding of SEK 31,6 million to progress the company´s drug development programs. The financing is being implemented as a convertible loan with attached share options, directed toward a consortium of investors that includes Karolinska Development, AB Ility, and Ribbskottet AB, but also other current shareholders in Umecrine Cognition AB.

Umecrine Cognition is developing a new class of drugs to alleviate cognitive symptoms. The company's most advanced drug candidate, golexanolone, is currently being developed for the treatment of patients with primary biliary cholangitis (PBC) and hepatic encephalopathy (HE; liver coma). These severe conditions lead to reduced brain function, causing extreme fatigue, difficulty concentrating, and impaired motor function. Results from previous clinical and pre-clinical studies strongly indicate that golexanolone can counteract such reduced brain function. The company is initiating a clinical Phase 2 study of golexanolone in PBC to investigate the drug candidate's safety profile, pharmacokinetics, and preliminary efficacy in a targeted patient population.

Recently, Umecrine Cognition also presented results showing that golexanolone improved cognitive and motor alterations in a preclinical model of Parkinson's disease. The results showed that golexanolone also reverses non-motor dysfunctions such as fatigue, anxiety, and depression. To further evaluate golexanolone's potential role in the treatment of this progressive and debilitating CNS disease, Umecrine Cognition aims to conduct mechanistic studies.

"Umecrine Cognition continues to create value for its stakeholders by progressing the development of golexanolone. With this additional funding, we have secured further resources not only for the clinical Phase 2 study in PBC patients but also for the evaluation of golexanolone in preclinical models of Parkinson's disease. This broadens the scope for our drug candidate as a potential treatment of orphan diseases as well as more common CNS diseases," said Anders Karlsson, CEO of Umecrine Cognition.

Umecrine Cognition was granted Orphan Drug Designation (ODD) for golexanolone, a novel neurosteroid-based drug candidate, for the treatment of PBC in January 2023.

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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, ultimately leading 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 company has reported the elevation of neurosteroid levels 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 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 November 3, 2021 (https://www.umecrinecognition.com/en/umecrine-cognition-presents-data-showing-improved-symptoms-in-a-model-of-parkinsons-disease-following-treatment-with-golexanolone/)

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

Attachments

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