

Karolinska Development's portfolio company Umecrine Cognition presents new data supporting the development of golexanolone as a treatment of primary biliary cholangitis

STOCKHOLM, SWEDEN – November 3, 2021. Karolinska Development AB (Nasdaq Stockholm: KDEV) announces today that the portfolio company Umecrine Cognition will present new scientific results showing that the innate neurosteroid allopregnanolone plays an important role in the development of cognitive symptoms observed in patients with primary biliary cholangitis (PBC). Since Umecrine Cognition's drug candidate golexanolone could potentially impact allopregnanolone the company has, based on the novel clinical results and other supportive data, initiated preparations for a Phase 2 clinical study in PBC. Umecrine Cognition will present the data at The Liver Meeting Digital Experience™ 2021, the premier Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), which takes place November 12-15.

Umecrine Cognition is developing golexanolone, a novel drug candidate that counteracts the effect of allopregnanolone on GABA_A receptors, thereby restoring normal nerve signalling in the brain. Golexanolone is currently in clinical development for hepatic encephalopathy.

In a recently conducted study, in collaboration with Newcastle University and the UK-PBC organization, Umecrine Cognition evaluated the association between allopregnanolone and health related quality of life in patients with primary biliary cholangitis (PBC), using a validated and trusted disease-specific measure (PBC-40). In the study, serum allopregnanolone levels were analyzed in 160 subjects, including 120 PBC patients and 40 age- and gender-matched healthy controls. Further, serum allopregnanolone was compared across the PBC-40 domains for those exhibiting no or mild symptoms and those exhibiting severe symptoms.

The study results revealed two key insights. Firstly, elevated serum levels of allopregnanolone were significantly associated with severe cognitive and emotional symptoms ($p=0.02$ and $p=0.004$, respectively) as well as with itch ($p=0.03$). These results align well with what is expected from drug interactions with GABA_A receptors. Secondly, the results indicate that younger age was predictive of significantly higher allopregnanolone levels within the PBC cohort ($p<0.001$), but not in healthy controls ($p=0.119$). In association, younger age was coupled to more severe cognitive symptoms (severe vs. none; $p=0.001$). Based on these new findings and other supportive data, Umecrine Cognition has decided to prepare a Phase 2 clinical trial in PBC patients.

"Umecrine Cognition's recent research finding, identifying golexanolone's drug target allopregnanolone as a novel serum biomarker for fatigue and cognitive disturbances in primary biliary cholangitis, paves the way for expanding the clinical development of golexanolone to this medically underserved disease," comments Viktor Drvota, CEO of Karolinska Development.

Primary biliary cholangitis is a chronic autoimmune disease that attacks the bile ducts and can result in liver cirrhosis. Most people affected are women aged 40-60 years. There is currently no cure for the disease. As the liver is attacked, the level of inflammation in the brain increases, leading to personality changes, confusion and decreased consciousness. Around 190,000 patients are currently living with the disease in the seven largest geographical pharmaceutical markets.

The study results will be presented at The Liver Meeting Digital Experience™ under the topic "Cholestatic and autoimmune liver disease" A link to the abstract can be found here: <https://aasldpubs.onlinelibrary.wiley.com/doi/epdf/10.1002/hep.32188> (no. 1282).

Karolinska Development's direct ownership interest in Umecrine Cognition amounts to 70%.



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TO THE EDITORS

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Karolinska Development AB (Nasdaq Stockholm: KDEV) is a Nordic life sciences investment company. The company focuses on identifying breakthrough medical innovations in the Nordic region that are developed by entrepreneurs and leadership teams. The Company invests in the creation and growth of companies that advance these assets into commercial products that are designed to make a difference to patients' lives while providing an attractive return on investment to shareholders.

Karolinska Development has access to world-class medical innovations at the Karolinska Institutet and other leading universities and research institutes in the Nordic region. The Company aims to build companies around scientists who are leaders in their fields, supported by experienced management teams and advisers, and co-funded by specialist international investors, to provide the greatest chance of success.

Karolinska Development has a portfolio of ten companies targeting opportunities in innovative treatment for life-threatening or serious debilitating diseases.

The Company is led by an entrepreneurial team of investment professionals with a proven track record as company builders and with access to a strong global network.

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