

Karolinska Development's portfolio company Umecrine Cognition submits a Clinical Trial Application to initiate a phase 2 clinical trial with golexanolone

STOCKHOLM, SWEDEN – May 19, 2022. Karolinska Development AB (Nasdaq Stockholm: KDEV) today announces that its portfolio company Umecrine Cognition has submitted a clinical trial application (CTA) to the Hungarian regulatory body OGÝEI for approval to initiate a Phase 2 clinical trial of its drug candidate golexanolone in patients suffering from primary biliary cholangitis. The study is planned to be conducted at several European clinical trial centers.

Umecrine Cognition's drug candidate golexanolone represents a novel drug class that modulates the activity of the GABA_A receptor in order to counteract cognitive impairment associated with liver disease and associated inflammation in the brain. Golexanolone is being developed in the indications of primary biliary cholangitis (PBC), which leads to inflammation and degeneration of the bile ducts, and hepatic encephalopathy (HE).

The randomized, double-blind, placebo-controlled Phase 2 clinical trial will compare golexanolone to placebo in up to 150 patients with non-cirrhotic liver or Child-Pugh class A cirrhotic PBC who, despite treatment with conventional therapy, show clinically significant fatigue and cognitive symptoms. The study will be conducted in two phases – part A and part B. In part A, the study will evaluate the pharmacokinetics, safety and tolerability of the drug candidate. In part B, the safety and tolerability will be further evaluated, as well as the preliminary treatment effect of golexanolone in the same patient population.

The study is expected to start in the summer of 2022. The results from part A are expected to be presented before the end of the year and the results of part B in the second half of 2023. The full results of the study are expected to be presented in 2024.

"The submission of the Clinical Trial Application to the Hungarian regulatory body OGÝEI means that preparations for the planned Phase 2 study of Umecrine Cognition's drug candidate golexanolone are now entering their final stages. Golexanolone has the potential to revolutionize the treatment of cognitive disorders in patients with liver disease, and a favourable outcome of the study would be a major step towards this goal," said Viktor Drvota, CEO, Karolinska Development.

Karolinska Development's ownership in Umecrine Cognition amounts to 73 percent.

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TO THE EDITORS

About Karolinska Development AB

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 nine 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.

For more information, please visit www.karolinskadevelopment.com