

## **Karolinska Development's portfolio company Umecrine Cognition presents positive safety data from the first part of its Phase 1b/2 study in PBC**

STOCKHOLM, SWEDEN – March 22, 2024. Karolinska Development AB (Nasdaq Stockholm: KDEV) today announces that its portfolio company Umecrine Cognition has presented a positive safety data from the first part of its clinical Phase 1b/2 study of golexanolone in patients with Primary Biliary Cholangitis, PBC. The second part of the study, which will now be initiated, aims to evaluate the preliminary efficacy of the drug candidate and further study its safety and tolerability profile. Top-line results are expected in H1, 2025.

Umecrine Cognition is developing a new class of drugs to treat cognitive symptoms caused by liver disease. The company's lead drug candidate, golexanolone, is currently being evaluated in a randomized, double-blind, placebo-controlled, clinical Phase 1b/2 study in patients with primary biliary cholangitis (PBC) who experience clinically significant fatigue and cognitive symptoms. The first part of the study aimed to evaluate golexanolone's safety and tolerability profile, as well as the pharmacokinetic profile, and the data generated provided important guidance on the dosing intervals in the second part of the study.

The study's internal safety review committee (iSRC) has authorized the initiation of the second part of the study without dose adjustments and the first patient is expected to be included during the second quarter. Approximately 84 subjects will be randomized to the second part of the study which aims to investigate preliminary treatment efficacy signals. The evaluation also includes a planned interim analysis when a third of the patients have been included. Top-line results are expected in H1, 2025.

"In previous clinical and preclinical studies, Umecrine Cognition's drug candidate golexanolone has shown strong potential to counteract an incorrect suppression of brain activity, causing extreme fatigue and difficulty with concentration. We are happy that the current study is progressing and look forward to the results from the second part," says Viktor Drvota, CEO of 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 patient's 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 eleven 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](http://www.karolinskadevelopment.com).