

Karolinska Development's portfolio company Umecrine Cognition presents positive additional results from a phase 2a study of golexanolone

STOCKHOLM, SWEDEN – May 8, 2020. Karolinska Development AB (Nasdaq Stockholm: KDEV) today announces that its portfolio company Umecrine Cognition has presented positive supplementary results from a phase 2a study of golexanolone. Analyses of data for additional efficacy endpoints reveal that treatment with the drug candidate exerts a significant effect on brain signaling with a correlated positive effect on excessive daytime sleepiness, a disabling symptom of a range of CNS-related disorders. Umecrine Cognition will revisit the development strategy for golexanolone, in order to optimize the value of its drug candidate based on these encouraging findings.

Top-line data from the phase 2a study of golexanolone in patients with liver cirrhosis and mild hepatic encephalopathy (HE) was presented in April 2020. As previously reported, subjects in all treatment groups showed directionally favorable improvements in cognitive function, but no statistically significant difference between golexanolone and placebo was observed what regards the specific outcome measures utilized.

An in-depth analysis of additional efficacy endpoints has now been performed, revealing significant changes (p=0.021) in brain activity as assessed by spectral EEG (electroencephalogram) analysis. Spectral EEG is a highly sensitive measurement method that enables objective tracking of a pharmaceutical compound's potential impact on the electrical activity in the brain and also a recognized and accepted measure of covert/minimal HE. The results of this prespecified analysis strongly indicates that golexanolone exerts a pharmacological effect in the brain even at the lowest dose of 10 mg bid. An improvement in the EEG is regarded as an improvement in HE. Importantly, the new in-depth analysis also shows a corresponding and statistically significant improvement (p=0.047) of excessive daytime sleepiness as assessed by ESS (Epworth Sleepiness Scale). This finding is well aligned with what has been observed in a previous study of golexanolone in healthy adults.

Excessive daytime sleepiness is a debilitating condition that can be caused by a range of medical and psychiatric conditions such as hepatic encephalopathy, primary biliary cholangitis, Alzheimer's disease and schizophrenia. Due to the limitations of current treatment options, there is a strong demand for therapies with new mechanisms of action such as the potential first-in-class compound golexanolone .

"The extended analysis of the phase 2a data reveals a compelling opportunity to assess golexanolone as a potential treatment of excessive daytime sleepiness, an incapacitating condition that appears in hepatic encephalopathy and several CNS disorders. We are looking forward to supporting Umecrine Cognition in its efforts to compile a revised strategy for its lead drug candidate, based on these encouraging findings", says Viktor Drvota, CEO of Karolinska Development.

Further information about golexanolone and the updated results of the phase 2a study will be issued by Umecrine Cognition in a separate press release, please visit www.umecrinecognition.com.

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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 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.

For more information, please visit www.karolinskadevelopment.com

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