

## **Karolinska Development's portfolio company Umecrine Cognition announces results from a phase 2a clinical study of golexanolone**

STOCKHOLM, SWEDEN – April 3, 2020. Karolinska Development (Nasdaq Stockholm: KDEV) announces that its portfolio company Umecrine Cognition has reported top-line data from a clinical phase 2a study of the drug candidate golexanolone in patients at risk of developing hepatic encephalopathy. Results demonstrate a positive safety and tolerability profile; however, no indications of clinical effects could be observed. The results will be further analyzed in order to evaluate if continued clinical development of golexanolone is merited. Such a decision is planned within the second quarter of 2020, at which point Karolinska Development will disclose the impact on the book value of its holding in Umecrine Cognition.

The intended use of golexanolone (GR3027) is to reduce cognitive impairment and other severe CNS symptoms, and the risk of hepatic encephalopathy (HE) episodes. HE is a neurological and psychiatric condition which occurs due to liver failure.

The double blinded, randomized, placebo-controlled phase 2a study was conducted in 45 patients who were treated twice a day with golexanolone (10, 40, or 80 mg) or placebo for 21 days. The study participants were patients with diagnosed liver cirrhosis, without HE but with a confirmed abnormal cognitive status. Treatment effect was measured using three internationally renowned methods to deduce the grade of symptoms during HE – CRT (continuous reaction time) and PHES (psychometric encephalopathy score) and ANT (animal naming test). Additional parameters, for which data is yet not available for analysis, were evaluated during the study. These include neurophysiological assessment of brain activity (EEG), the level of excessive daytime sleepiness. (ESS), assessment of caregiver burden and evidence of overt hepatic encephalopathy.

In the study, golexanolone exhibited a favorable safety and tolerability profile. Measurements of drug plasma concentrations showed that on a group level patients who received active treatment had systemic exposure of the drug candidate. At the end of the study, a tendency for improvement in cognitive functions was observed based on all individual evaluation methods (CRT, PHES and ANT). However, no differences were observed between patients who had received the active treatment and patients who had received placebo. Additionally, no differences in efficacy were noted between the three different doses of golexanolone.

“The top-line data from the phase 2a-study shows that golexanolone demonstrates a positive safety and tolerability profile; however, the absence of a clinical effect is discouraging. As soon as a complete set of the study's results are compiled, these will be analyzed thoroughly together with leading international experts in the field of hepatic encephalopathy. Subsequently, an evaluation will be made on whether necessary prerequisites for further development is at hand”, says Viktor Drvota, CEO of Karolinska Development

The book value of Karolinska Development's holding in Umecrine Cognition amounts to SEK 378 million as per December 31, 2019.

### **For further information, please contact:**

Viktor Drvota, CEO, Karolinska Development AB  
Phone: +46 73 982 52 02, e-mail: viktor.drvota@karolinskadevelopment.com

## **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](http://www.karolinskadevelopment.com)

*This information is information that Karolinska Development AB (publ) (Nasdaq Stockholm: KDEV) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of Viktor Drvota, at 18:05 CET on 3 April 2020.*