

Karolinska Development company Umecrine Cognition announces positive Phase 1 data with GR3027 in hepatic encephalopathy

STOCKHOLM/UMEÅ – 3 November, 2016. Karolinska Development's portfolio company Umecrine Cognition AB, today announces positive top-line results from its Phase 1 first in human clinical trial with GR3027, a novel orally active GABA_A receptor modulating steroid antagonist, in development for treatment of hepatic encephalopathy (HE) in patients with liver cirrhosis. The study demonstrated that GR3027 was safe and well tolerated, and also showed CNS target engagement.

Details from the Umecrine Cognition press release follow:

"We are very encouraged by the pharmacodynamic effect of GR3027 in our Phase 1 trials, along with its favorable safety and tolerability profile," said Magnus Doverskog, CEO of Umecrine Cognition. "These findings show that oral GR3027 reaches the brain target with an expected mechanism of action and combined with our previous pre-clinical results [1] support our belief that GR3027 could be an attractive new therapy for patients with liver cirrhosis and hepatic encephalopathy."

Victor Drvota, Chief Investment Officer at Karolinska Development, said: "Umecrine Cognition's strong early clinical results, together with its recent financing round, has placed the company in an excellent position to advance GR3027 into the next clinical studies needed to establish clinical proof of concept, a value inflection point."

Umecrine Cognition's lead candidate GR3027 is designed to reduce GABA_A receptor mediated inhibition of brain function by antagonizing endogenous inhibitory neurosteroids such as allopregnanolone. Enhanced GABA_A receptor mediated signaling is a key driver for the neurological symptoms associated with HE. In the current trial, GR3027 was found to be well tolerated with no serious adverse events reported and with dose proportional pharmacokinetics. Assessment of Saccadic Eye Velocity and self-rated sedation after a challenge with allopregnanolone showed evidence that orally administered GR3027 antagonizes neurosteroid modulation of GABA_A receptor function.

The primary objectives of the study were to evaluate the safety and tolerability of GR3027 after single dose administration in healthy volunteers and to identify the Maximum Tolerated Dose (MTD) or the Study Maximal Dose (SMD), if the MTD was not reached. The secondary objectives were to determine the single oral dose PK characteristics of GR3027 in healthy volunteers and to evaluate the capacity of GR3027 to antagonize allopregnanolone-induced activation of GABA_A as determined by its pharmacodynamic effects on Saccadic Eye Velocity (SEV) and self-rated sedation.

In the first part, 48 subjects were randomized to receive either GR3027 or placebo (6:2) at doses ranging from 1 mg to 200 mg. None of the pre-specified dose escalation stopping criteria were obtained and GR3027 was found to be well tolerated throughout the dose range up to the SMD of 200 mg. The pharmacokinetic profile obtained displayed dose linearity over the dose range applied.

In the second part of the study, 18 subjects were randomized in a three-part cross-over design to receive either GR3027 at 3 mg (low dose) or 30 mg (high dose), or placebo. As expected,

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allopregnanolone administration decreased SEV in the placebo group. Prespecified statistical analysis of the difference between treatment groups with GR3027 and placebo showed a significant improvement with GR3027 in the high dose group ($p=0.03$; Wilcoxon Signed Rank Test). The results also provide evidence that the impaired self-rated sedation produced by allopregnanolone was also improved by GR3027.

The company plans to announce further details and data of the trial at the 9th International Meeting – Steroids and Nervous System in Torino, Italy (February 11-15, 2017).

For further information, please contact:

Jim Van heusden, CEO, Karolinska Development AB
Phone: +46 72 858 32 09, e-mail: jim.van.heusden@karolinskadevelopment.com

Christian Tange, CFO, Karolinska Development AB
Phone: +46 73 712 14 30, e-mail: christian.tange@karolinskadevelopment.com

David Dible/Mark Swallow/Pip Batty, Citigate Dewe Rogerson
Phone: +44 20 7638 9571; e-mail: KDev@citigatedr.co.uk

TO THE EDITORS

About Umecrine Cognition AB

Umecrine Cognition, a Karolinska Development (Nasdaq Stockholm: KDEV) portfolio company, is developing a potential therapy that represents a new target class relevant for several major CNS-related disorders. The primary focus is to develop a treatment for life-threatening overt Hepatic Encephalopathy and long-term treatment in minimal Hepatic Encephalopathy in patients with liver disease, a growing area with high unmet medical need. The current lack of therapeutics that directly addresses the neurocognitive signs and symptoms of Hepatic Encephalopathy makes a novel treatment likely to become a major contribution for the treatment of this disorder. For more information, please visit www.umecrinecognition.com

About Karolinska Development AB

Karolinska Development AB (Nasdaq Stockholm: KDEV) is a Nordic life sciences investment company. The company focuses on identifying medical innovation and investing in the creation and growth of companies developing these assets into differentiated products that will make a difference to patients' lives and provide an attractive return on investment to its shareholders.

Karolinska Development has access to world-class medical innovations at leading universities and research institutes in the Nordic region, including the Karolinska Institutet. The Company aims to build companies around innovative products and technologies, supported by experienced management teams and advisers, and co-funded by specialist international life science investors, to provide the greatest chance of success.

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Karolinska Development's portfolio comprises 10 companies focusing on the development of innovative treatment for life-threatening or serious debilitating diseases.

The Company is led by a team of investment professionals with strong investment backgrounds, experienced company builders and entrepreneurs, with access to a strong global network.

For more information, please visit www.karolinskadevelopment.com

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