Umecrine Cognition announces on-line publication of Clinical trial results perteining to GR3027 safety, pharmacokinetics and CNS target engagement

STOCKHOLM. Umecrine Cognition AB is pleased to announce the publication in Psychopharmacology of clinical trial results which demonstrate that the company's candidate drug, GR3027, reverses the brain-inhibitory effects of allopregnanolone at doses which are well tolerated and exhibit excellent pharmacokinetics.

The publication by Johansson et al. describes the safety and pharmacokinetic results from protocol UCAB-CT-01 and the still ongoing protocol UCAB-CT-02 pertaining to single and multiple ascending doses of GR3027 in healthy adults as well as the ability of GR3027 to mitigate the inhibitory effect on the brain of intravenously administered allopregnanolone.

The single- and multiple ascending dose trials enrolled a total of 90 healthy adult male subjects and demonstrated excellent pharmacokinetic characteristics and tolerability without evidence of dose-limiting toxicity up to single oral doses of 200 mg and steady state dosing up to 100 mg BID. The results of the randomized, controlled and double-blinded allopregnanolone challenge study, previously reported in abstract form, indicate that GR3027, administered orally at single doses of 3 or 30 mg, well within the range exhibiting excellent pharmacokinetics and tolerability, enters the CNS and mitigates the inhibitory effects of allopregnanolone on brain function.

The GABA-system, the major inhibitory neurotransmitter system in the human brain, regulates diverse CNS functions including learning, memory, sedation and sleep and is a validated pharmacological target. Attempts to develop GABAA receptor antagonists have been hindered by their propensity to induce seizures. GR3027 represents a novel class of neurosteroid-modulating drugs designed to normalize GABAergic neurotransmission without the safety risks associated with GABAA receptor antagonists.

"Publication of these peer-reviewed clinical data represents an important milestone for Umecrine Cognition," commented Magnus Doverskog, Umecrine Cognition CEO. "The encouraging results substantially de-risk development of this promising new therapeutic intended to treat hepatic encephalopathy, hypersomnolence and potentially other disorders attributable to neurosteroid-mediated over-activation of GABAergic transmission."

The article, "GR3027 reversal of neurosteroid-induced, GABAA receptor-mediated inhibition of human brain function: an allopregnanolone challenge study", can be accessed via the Psychopharmacology website https://link.springer.com/article/10.1007/s00213-018-4864-1 [Johansson, M., Månsson, M., Lins, LE. et al. Psychopharmacology (2018)].

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TO THE EDITORS

About Umecrine Cognition AB
Umecrine Cognition is developing a potential therapy that represents a new target class relevant for several major CNS-related disorders. The lead compound GR3027 presently in clinical development is positioned primarily as a novel therapy for the treatment of hepatic encephalopathy in patients with cirrhosis and for the treatment of excessive daytime sleepiness in patients with central disorders of hypersomnolence. For more information, please visit www.umecrinecognition.com.