Umecrine Cognition announces first patient included in clinical Phase 2a study in patients with sleep disorder

STOCKHOLM – November 20, 2017. Umecrine Cognition AB, a Karolinska Development (Nasdaq Stockholm: KDEV) portfolio company, today announces the inclusion of the first patient in a clinical Phase 2a study with the lead compound GR3027 in patients with idiopathic hypersomnia.

The objectives of the study (protocol UCAB-CT-03) are to assess the safety and pharmacokinetics, and to evaluate the exploratory efficacy of GR3027 in patients with idiopathic hypersomnia.

Idiopathic hypersomnia (IH) is a severe orphan disease characterized by chronic excessive daytime sleepiness (EDS). It is a lifelong debilitating condition with a profound effect on the patient's quality of life. There are no approved treatments for IH but several wake-promoting treatments are used off-label. However, they are inadequate to alleviate symptoms in most patients, and medication-refractory symptoms or medication intolerance prevents control of symptoms in approximately one-quarter of IH patients.

GR3027, in clinical development for hepatic encephalopathy and sleep disorders, is a $GABA_A$ receptor modulating steroid antagonist (GAMSA) designed to antagonize $GABA_A$ receptor activation by endogenous neuroactive steroids. GR3027 has been shown to restore different types of neurological impairments including cognitive and sleep alternations in experimental models. The drug candidate enters the CNS and reverses the inhibitory effects of the neurosteroid allopregnanolone on brain function in humans. Collectively, these findings strongly implicate that GR3027 is a promising novel treatment for a wide range of cognitive and sleep disorders.

"Excessive daytime sleepiness is a major concern from a medical and public health point of view, with a global prevalence of approximately 20%", said Magnus Doverskog, CEO of Umecrine Cognition, and concludes "we are excited to start exploring GR3027 in patients with idiopathic hypersomnia, a subset of patients with lifelong chronic sleeping disorders that severely affect their lives."

About the GR3027 Phase 2a study in idiopathic hypersomnia
The phase 2a study of GR3027 in patients with idiopathic hypersomnia (IH) includes an open-label part to assess safety, tolerability and pharmacokinetics of a single oral GR3027 dose in six female patients with IH (Part A) followed by a prospective, double-blind, randomized, placebo-controlled crossover study in male and female IH patients (Part B). Part B will enroll up to 14 male and female IH patients to assess safety, tolerability, exposure, and preliminary efficacy of multiple oral doses of GR3027.

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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.