

Umecrine Mood reports preliminary data from exploratory Phase II study in premenstrual dysphoric disorder (PMDD)

STOCKHOLM – June 12, 2014. Umecrine Mood AB announced today data from an exploratory Phase II study with its candidate drug UC1010 in patients with PMDD. The primary end point was not met in the study but a post hoc analysis indicate positive treatment effects in a subgroup of patients with the most severe problems. UC1010 was well tolerated and there were no safety concerns. Karolinska Development owns 38% of the Umecrine Mood.

Most women experience some form of premenstrual symptoms but in about five percent of young and middle-aged women that have PMDD, the symptoms are so severe that they in a debilitating way affect daily life and relationships to other people. The severity of the symptoms confers huge costs on society.

In an exploratory double blind, randomized multicenter study, 120 patients with PMDD received, during one menstrual cycle, either placebo or one of two different doses of the drug candidate UC1010, a GABA-A modulating steroid antagonist (GAMSA). The objectives of the trial were to study the safety and effect of UC1010. The primary end point in the study was to assess symptoms using a validated daily rating scale (DRSP) containing the sum of the four cardinal symptoms for diagnosis of PMDD measured as the average score during the late luteal phase (the premenstrual week) in the active dose arms combined vs. placebo.

The outcome of the study shows a reduction in the average late luteal phase score after treatment vs. before treatment of 61% in the active group and 55% in the placebo group. The difference between the active group and placebo was not statistically significant and the primary end-point of the study was thus not met. In a post hoc analysis there was a statistically significant difference ($p < 0.05$) between active treatment and placebo in patients with severe problems during a week or more per cycle. Moreover, differences were observed in the PMDD symptoms that are clinically most relevant. There were no safety concerns with UC1010 and it was well tolerated.

"PMDD symptoms occur following ovulation and are suggested to be related to the action of progesterone metabolites on the brain's emotional center to which PMDD patients are especially sensitive. Umecrine Mood is the first company to develop compounds with an entirely new mechanism of action that inhibit the activity of these metabolites. The study has demonstrated a good safety profile and warrants further analyses", says Karin Ekberg, CEO of Umecrine Mood.

"While the primary endpoint was not met there are findings that need to be further analyzed in this exploratory trial before we can decide on the next steps", says Torbjörn Bjerke, CEO of Karolinska Development AB.

Note: Ownership of 38% includes indirect ownership through KDev Investments AB and KCIF Co-Investment Fund KB.

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TO THE EDITORS

About Umecrine Mood

Umecrine Mood develops novel products to treat symptoms associated with Premenstrual Dysphoric Disorder (PMDD) caused by an endogenous CNS-active steroid derived from the corpus luteum of the ovary. The company portfolio includes newly discovered lead compounds and the selected drug candidate is a first-in-class compound that inhibits the provocateur to act on the emotional center of the brain. For more information, please visit www.umecrine.se/mood

About Karolinska Development AB

Karolinska Development aims to create value for patients, researchers, investors and society by developing innovations from world class science into differentiated products that can be partnered. The business model is to: SELECT the most commercially attractive medical innovations that can potentially satisfy unmet medical needs; DEVELOP innovations to the stage where the greatest return on investment can be achieved; and COMMERCIALIZE the innovations through the sale of companies or out-licensing of products. An exclusive deal flow agreement with Karolinska Institutet Innovations AB, along with other cooperation agreements with leading universities, delivers a continuous flow of innovations. Today, the portfolio consists of 34 projects, of which 17 are in clinical development. For more information, please visit www.karolinskadevelopment.com.

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