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Umecrine Mood announces positive results from an exploratory Phase I/II study with UC1010 in premenstrual dysphoric disorder (PMDD)

Stockholm – September 19, 2014. Umecrine Mood AB announced today the final results from an exploratory randomized Phase I/II study with its candidate drug UC1010 in patients with PMDD. The results show a statistically significant improvement of symptoms in patients treated with UC1010 compared to placebo. Umecrine Mood is a Karolinska Development portfolio company.

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 debilitating that they affect normal daily life, work and relationships. The severity of the symptoms confers huge costs on society.

Umecrine Mood's candidate drug UC1010 is a first-in-class therapy for PMDD. UC1010 has been developed specifically to target the atypical effects of progesterone metabolites on GABA-A receptor activity in the brain, believed to underlie key PMDD symptoms.

In an exploratory double blind, randomized multicenter study, 120 patients with PMDD received placebo or one of two doses of UC1010 during one menstrual cycle. The objectives of the trial were to study the safety and efficacy of UC1010. The primary efficacy end-point was assessed using a validated daily rating scale (DRSP), to measure the average late luteal phase symptoms in patients treated with UC1010 vs. those given placebo. As previously reported, the primary efficacy end-point of the study was not met.

Following final analysis of the study data, we report here that UC1010 elicits a highly statistically significant reduction of symptoms in PMDD patients that have taken the drug according to the intended treatment regimen. The post-hoc analysis revealed two key variables that impacted the study outcome:

1. Despite patient randomization, the baseline follicular phase symptoms showed a skewed distribution between study groups. Recalculation of results to correct for individual follicular symptoms reveals a statistically significant improvement of symptoms by UC1010 compared to placebo in the total study population ($p<0.05$ for the total premenstrual symptom score).

2. More significantly, due to inconsistencies in the assessment of ovulation, 32% of patients did not receive treatment as intended according to the protocol. Inclusion only of patients treated as intended shows there were highly significant beneficial effects of UC1010 (both doses) compared to placebo, both for the cardinal PMDD symptoms ($p=0.003$) and total premenstrual symptom scores ($p=0.006$) as well as for the impairment score ($p=0.01$), which specifically measures the impact of symptoms on daily life in the week prior to menstruation.

There were no safety concerns with UC1010 and it was well tolerated.

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Marie Bixo, Principle Investigator, said: “These results are very encouraging and well in line with effects seen in other studies (using antidepressants), with the added bonus that UC1010 is safe and well tolerated, with none of the side-effects seen with other agents used for PMDD treatment”.

Karin Ekberg, CEO of Umecrine Mood, commented: “This exploratory Phase I/II trial is the first to show a beneficial effect of a novel mechanism-based therapy to treat a condition affecting a large proportion of women. We have learned some important lessons from this initial study and are now well-positioned to move forward to conduct a definitive Phase II clinical trial”.

Note: Karolinska Development owns 38% of Umecrine Mood including indirect ownership through KDev Investments AB, KCIF Co-Investment Fund KB and Umecrine AB.

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TO THE EDITORS

About Umecrine Mood AB
Umecrine Mood is developing novel products to treat symptoms associated with premenstrual dysphoric disorder (PMDD), a debilitating condition that affects 3-8% of women worldwide. The company’s lead candidate drug is a first-in-class compound, currently in Phase II clinical development that inhibits the negative effects of progesterone metabolites on key mood pathways in 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 33 projects, of which 16 are in clinical development. For more information, please visit www.karolinskadevelopment.com.

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