PRESS RELEASE
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Asarina Pharma reports topline results from Phase IIb study in PMDD

(Stockholm April 21, 2020) **Asarina Pharma AB (publ) today released topline results from its Phase IIb study with Sepranolone for the treatment of PMDD (premenstrual dysphoric disorder). The study demonstrates a positive safety and tolerability profile for Sepranolone. However, while a substantial reduction in PMDD symptoms was achieved across the patient population, a statistically significant difference compared to placebo was not observed for the study's primary and secondary endpoints, due to the unexpectedly high placebo effect. Asarina Pharma will continue its fully financed development programs for Sepranolone in menstrual migraine and Tourette syndrome, where disease mechanisms are different and clinical endpoints are more objective and robust.**

"Obviously, we had hoped for a different outcome" says Peter Nordkild, CEO of Asarina Pharma. "To all women living with PMDD I can only express my shared disappointment about the study outcome. Maybe more than most we understand the enormity of the need for a treatment for PMDD, but also the incredibly complex symptomatology. We hope that our research around allopregnanolone will play an important part in the collective understanding of PMDD, and that this study has been valuable in raising awareness of and attention to this devastating condition."

Asarina Pharma Chief Medical Officer Märta Segerdahl: "It is comforting to see that Sepranolone remains safe and well tolerated. We know that levels of allopregnanolone are elevated in the brain in both menstrual migraine and Tourette patients, and that Sepranolone is the body's endogenous compound that inhibits the effect of allopregnanolone. We remain optimistic that Sepranolone may be developed as an effective treatment for Tourette syndrome and menstrual migraine."

ABOUT THE STUDY
The phase IIb study was a randomized, double-blind, placebo-controlled study taking place in 14 study centers in Sweden, the UK, Poland and Germany. 206 patients, average age 33 years, were randomized after completing the screening. 547 menstrual cycles were evaluated, the average menstrual cycle length in baseline cycles was 28.1 days with 90 percent of cycles having less than ±2 days cycle length difference. Patients administered their own 0.4 mL injections using a prefilled single-use syringe. Two doses were administered, 10 and 16 mg per dose. Treatment began 14 days prior to estimated start of next menstruation, running every second day during the luteal phase up until the beginning

of menstruation, with a maximum 7 doses per cycle. Patients filled in a daily rating of severity of problems, DRSP, of 11 PMDD symptoms.

The primary endpoint of the study was calculated from the late luteal phase total symptom score (LmaxSum21), as the difference between the average scores of two baseline cycles and the average score in the treatment cycles. The reduction in these scores was compared between actively treated and placebo treated patients. The average baseline score was 85 points, corresponding to patients having moderate to severe PMDD symptoms. Study treatment reduced the effect score by 27.9 points in the placebo group, compared to 30.3 in the active Sepranolone group, resulting in minimal to mild PMDD symptoms during treatment. The high placebo response may reflect the effect for some study patients of receiving positive attention of their disease having been unrecognized for many years.

In all, more than 2,000 doses of Sepranolone were taken during the study. One out of five patients reported injection site discomfort, no one reported severe discomfort. Overall, study data demonstrate that Sepranolone was well-tolerated with no safety signals.

In summary, Asarina Pharma's Phase IIb PMDD study did not meet its primary or secondary endpoints. However, Sepranolone treatment did show numerical improvement in all symptoms compared with placebo though these differences did not reach statistical significance.

ASARINA PHARMA GOING FORWARD

Asarina Pharma will continue to develop Sepranolone for menstrual migraine and Tourette syndrome in their respective fully funded Phase II trials. The menstrual migraine study is presently 80% recruited, and despite Coronavirus slowdown restrictions the company remains optimistic about delivering topline results in Spring 2021.

A **webcast with the possibility to ask questions** on the results is scheduled at 09.30 CET on April 22:
https://tv.streamfabriken.com/2020-04-22-asarina-pharma-press-conference

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About Sepranolone

Sepranolone (ISOALLO) is an active CNS steroid and endogenous compound produced naturally in the brain, especially during stress. It inhibits the effects of Allopregnanolone (ALLO). Following ovulation, progesterone is formed by the corpus luteum to prepare the uterus for a pregnancy. ALLO, a progesterone metabolite that enhances the $GABA_A$ system in different regions in the brain, is produced. For women with an altered sensitivity to ALLO this results in the negative mood symptoms of PMDD. ALLO is also produced as part of a stress reaction both in the brain and in the adrenal cortex. Sepranolone (ISOALLO) is the non-hormonally active steroid produced in the brain that inhibits the action of ALLO, so preventing the symptoms of PMDD from emerging. Sepranolone is highly specific, only inhibiting the effect of GABA steroid action on the receptor. It does not influence the effects of any other active $GABA_A$ receptor substances. Sepranolone has been demonstrated in animal models of PMDD, and in a clinical pharmaco-dynamic model that evaluated how a new family of compounds influences the GABA mechanisms in the brain. These compounds are called GAMSAs – $GABA_A$ Modulating Steroid Antagonists. Sepranolone is a GAMSA. Sepranolone is the first therapy specifically developed to treat PMDD.

About PMDD

Premenstrual dysphoric disorder (PMDD) is a severe neuroendocrinological condition affecting 4-8 percent of women of fertile age worldwide. The condition is often highly socially impairing with cyclical, often personality-altering symptoms that build up in the luteal phase (the two weeks before a period), peak in the week directly before menstruation, and then recede quickly when the period starts. Emotional symptoms include extreme mood changes, severe irritability and/or anger, depression, anxiety and feelings of hopelessness and low self-worth. In May 2019 PMDD received its own classification code, GA34.41, as a gynecological disease in the WHO International Classification of Diseases, ICD-11.

About Asarina Pharma

We are a Swedish biotech company developing Sepranolone for allopregnanolone-related stress and menstrual cycle neurological disorders. Our product pipeline is built on over 40 years of research into allopregnanolone-related neurological disorders. With our new family of GAMSA compounds ($GABA_A$ Modulating Steroid Antagonists) we aim to deliver a new generation of efficacious and safe drugs for still widely untreated neuroendocrinological conditions.