PRESS RELEASE
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Asarina Pharma reports topline results in Phase IIa Menstrual Migraine study

Asarina Pharma AB (publ) (ASAP: FN Stockholm) today releases topline results from its Phase IIa study of Sepranolone for the treatment of menstrual migraine. While a 25% reduction in menstrual migraine days was achieved across the patient population, a statistically significant difference compared to placebo was not obtained for the study's primary and secondary endpoints. The study confirms a positive safety and tolerability profile for Sepranolone. Asarina Pharma will continue its fully financed development program for Sepranolone in Tourette syndrome.

CEO Peter Nordkild: "Obviously we had hoped for a different outcome. This solid clinical study unfortunately does not confirm the scientific hypothesis that the pre-menstrual drop in allopregnanolone concentration, so called substance withdrawal syndrome, causes menstrual migraine. We remain committed to continue pursuing the development of Sepranolone for Tourette and Obsessive Compulsive Disorder, and it is vital to understand that the allopregnanolone withdrawal mechanism hypothesized as causing menstrual migraine is fundamentally different to the mechanism triggering Tourette and Obsessive Compulsive Disorder. Therefore, the lack of effect in menstrual migraine does not change the rationale for treatment of Tourette and OCD. Both of these indications, as demonstrated in preclinical effect models, are based on the direct effect of stress-induced allopregnanolone, as opposed to the hormonally induced increase in allopregnanolone in menstrual migraine."

CMO Märta Segerdahl: "In total more than 340 women have taken Sepranolone during its clinical development, with no severe adverse effects. We would like to thank all the participating patients for their dedicated participation in the study, and also the investigative sites and CRO collaborators for a very well conducted study. This especially in light of the restrictions incurred by the ongoing pandemic."

Sepranolone failed to demonstrate a statistically significant reduction in its primary clinical endpoint, the number of days with menstrually related migraine (2 days prior to menstruation and 5 days into the next menstrual cycle), compared to placebo. There were no effects demonstrated in secondary endpoints. The overall number of migraine days per menstrual period was reduced similarly for placebo and the two dose levels by approximately 1 day (25% reduction) of the menstrual migraine days. The 86 randomized patients had an average age of 38 years, a headache history of 21 years and prior to study treatment they had an average number of menstrual migraine days of 4 days every menstrual cycle.

Sepranolone demonstrated an excellent safety prolife in the study, with more than 1,200 doses of Sepranolone taken. One out of five patients reported some injection site discomfort, such as itching or a mild rash, no one reported severe discomfort. These mild side effects were transient. Overall, study data demonstrate that Sepranolone was well-tolerated with no safety signals.

About the study

The Phase IIa study was a randomized, double-blind, placebo-controlled study that took place at 7 study centers: 4 in Sweden and 3 in Finland. 164 patients were enrolled, 86 were randomized after completing the screening period. Patients self-administered 0.4 mL injections using a prefilled single-use syringe. Two dose levels were administered subcutaneously, either 10 or 16 mg per dose, or placebo. 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 detailed daily treatment assessment, reporting number of days with migraine, intensity of migraine pain, amount of symptomatic treatment taken, and a questionnaire on function and symptoms.

About Menstrual Migraine

Approx. 50 million women worldwide suffer from Menstrual Migraine. Unlike standard episodic migraine, MM attacks are predictable and recurring. MM is defined by the International Classification of Headache Disorders as migraine attacks that start up to two days before menstruation begins, continuing three or more days into the menstrual flow. MM is recognized as highly resistant to standard migraine therapies, including Triptans and CGRP antibodies.

About Sepranolone

Sepranolone is a patented, identical version of isoallopregnanolone – the endogenous neurosteroid that inhibits and regulates allopregnanolone and many of its negative symptoms. Asarina Pharma patented Sepranolone as a pharmaceutical formulation in 2010. Highly GABA-A receptor selective, Sepranolone has achieved an excellent safety profile in repeated studies.

The information above was provided by Asarina Pharma AB according to EU Market Abuse Regulations. The information was provided, through the contact person below, for publication on June 23, 2021 at 1905 CET.

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About Asarina Pharma

We are a Swedish biotech company developing Sepranolone for allopregnanolone-related stress, menstrual and 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.