



PRESS RELEASE

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Last Patient In for landmark PMDD study

Asarina Pharma AB (publ) (ASAP: FN Stockholm) today announced the last patient was enrolled in the Phase IIb study for its first-in-class compound Sepranolone for premenstrual dysphoric disorder (PMDD). Top-line results are on track for late March 2020.

“This is a crucial milestone. Full enrolment means we are on track to deliver top-line results in late March 2020 as promised. It also shows how large the unmet need and market potential is. PMDD is a devastating disorder afflicting 1-in-20 women of reproductive age worldwide,” said CEO Peter Nordkild.

Sepranolone reduced key symptoms by 80 percent with no side effects in Asarina Pharma’s Phase IIa trial. The current Phase IIb trial is the largest PMDD trial ever in Europe. More than 1.2 million women showed interest in Asarina Pharma’s study and almost 250,000 took the on-line screening questionnaire. Enrolment in the study is now completed with a total of 468 subjects screened which following the two initial diagnostic cycles should generate approximately 225 treated patients.

With top-line results in late March 2020, Asarina Pharma hopes to confirm Sepranolone as a safe, efficacious, highly targeted treatment for PMDD. The first ever—with no major side effects. Sepranolone is an endogenous compound and the first treatment to specifically target the neuro-hormonal mechanism that triggers PMDD.

The drop-out rate in the trial is unusually low; 15 percent compared to typically 30 percent in other late-stage PMDD studies.

“This fantastic compliance for a demanding trial says a lot about the treatment’s potential. For women enduring this condition these findings could mean a new chance to remain in control of their life,” says Nordkild.

Asarina Pharma COO Karin Ekberg leads the study, coordinating 14 sites in Poland, Germany, Sweden and England: “We’ve seen clinical and public awareness of PMDD growing throughout the trial. We’d like to thank all the women taking part in the trial who make it possible to bring Sepranolone towards the market. We’re delighted and proud of their passion and commitment.”

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About Asarina Pharma

We are a Swedish biotech company developing Sepranolone, the world's first dedicated treatment for premenstrual dysphoric disorder (PMDD) and other menstrual-related conditions. Our product pipeline is built on over 40 years' research into menstrual-related disorders like PMDD and menstrual migraine. With our new family of GAMSAs (GABA_A Modulating Steroid Antagonists), we aim to deliver a new generation of efficacious and safe drugs for still widely untreated conditions, thereby becoming a leading Women's Health company.

The information above was provided by Asarina Pharma AB according to EU Market Abuse Regulations. The information was provided, through the agency of the contact person above, for publication on August 15, 0800 CET, 2019.