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Sepranolone receives FDA IND approval in menstrual migraine

Asarina Pharma AB (publ) (ASAP: FN Stockholm) today announces the FDA has approved the IND for its lead compound Sepranolone in menstrual migraine. It is an important confirmation of Sepranolone's strong safety profile.

"The FDA IND approval in menstrual migraine is an important validation of the strong safety profile of our compound and also has very positive implications for our upcoming larger clinical PMDD trials." said Peter Nordkild, CEO of Asarina Pharma.

"All preclinical and clinical data on Sepranolone, over 100 documents in all, were submitted to the FDA for review and Sepranolone was cleared with an excellent safety profile. As a compound produced naturally in the body we expected that, but of course FDA confirmation is a crucial milestone." said Märta Segerdahl, Chief Medical Officer of Asarina Pharma.

Asarina Pharma will soon start its phase IIa proof-of-concept study in menstrual migraine in Finland, Denmark and Sweden with 80-90 patients aged 18-45 years. The study is expected to be completed by the end of 2020.

About menstrual migraine and Sepranolone

Menstrual migraine (MM) is a predictably recurrent, highly specific and disabling form of migraine. Approximately 50 million women worldwide suffer from MM, which is often resistant to standard migraine treatments. MM is triggered by the naturally produced neurosteroid allopregnanolone. Sepranolone inhibits allopregnanolone and might thus prevent the development of MM. Sepranolone is preventive, endogenous and the first compound to target the specific mechanism that triggers MM.

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About Asarina Pharma

Asarina Pharma is 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 GAMSA compounds (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 (publ) according to EU Market Abuse Regulations. (MAR) The information was provided, through the above contact person, for publication on July 9, 2019 at 0800.