

## Premenstrual Dysphoric Disorder recognized in new WHO International Classification of Diseases ICD-11

Stockholm, June 11, 2019: **Premenstrual dysphoric disorder (PMDD) has been given its own classification code and for the first time classified clearly as a gynaecological, not mental, disease in the WHO's new International Classification of Diseases, ICD-11. "This is a crucial step forward for future diagnosis, treatment and reimbursement of our lead indication" says CEO Peter Nordkild.**

*"The symptoms are severe enough to cause significant distress or impairment... and do not represent the exacerbation of a mental disorder".* So reads the new WHO ICD-11 definition of disease 'GA34.41', or PMDD. ICD-11 will, over the coming years, be the new international standard for classifying and reporting diseases, profoundly impacting how diseases are diagnosed, treated and reimbursed worldwide. PMDD, which affects 1-in-20 women of a fertile age worldwide, is Asarina Pharma's lead indication. The company's treatment, Sepranolone, is the first to specifically target PMDD, and is currently in a Phase IIb trial.

### NEW CLASSIFICATION WILL DRIVE NEW DIAGNOSES

The inclusion of PMDD in ICD-11 is an important confirmation of growing medical awareness of PMDD worldwide, and a growing scientific consensus that PMDD is a hormonal not psychiatric condition. PMDD is mentioned in the WHO's present ICD-10, but indirectly as a sub-classification under 'Premenstrual tension syndrome'. In ICD-11 PMDD is included as a clearly-named gynaecological disease with its own gynaecological classification code.

### DISEASE NOT SYNDROME, HORMONAL NOT PSYCHIATRIC

CEO Peter Nordkild: "For us the new classification is a fantastic vindication of our 40-years' plus research journey, confirming PMDD is not a mental health condition to be treated by a psychiatrist—but a neuro-hormonal disorder that falls squarely into the gynaecological remit, and which has proved to be treatable using our natural, endogenous compound Sepranolone."

ICD-11, the eleventh revision of the WHO's International Classification of Diseases, has been several years in development. It was formally adopted May 25 2019. From both the regulatory and reimbursement perspective, PMDD's inclusion as a gynaecological illness in ICD-11 could have profound implications for both PMDD and Sepranolone.

CBO Otto Skolling: "ICD-11 will come into effect in different counties in different years. Here in Sweden, for example, it will be implemented in 2022, which for us is ideal, as it is only a year or two before Sepranolone reaches the market. The new classification aligns powerfully with new diagnostic and regulatory trends around PMDD. We believe it will help women's health professionals worldwide identify and treat PMDD as a hormonal condition with Asarina's endogenous solution, rather than a mental condition to be treated with SSRIs, and

could positively impact the uptake, prescription and reimbursement for Sepranolone worldwide. Especially in countries where PMDD is still being reported and diagnosed as psychiatric. This new WHO classification gives all of us a really clear goal for identifying and treating this terrible condition correctly.”

**For further information, please contact:**

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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<sub>A</sub> 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.

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