



## PRESS RELEASE

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### First patient in for landmark Tourette Syndrome study

(Stockholm, 16 February, 2022.) **Asarina Pharma announces today that 'First Patient First Visit' has taken place in its phase IIa clinical study in Tourette syndrome at Bispebjerg University Hospital, Copenhagen. The Asarina compound being trialled, Sepranolone, is an endogenous neurosteroid that has already demonstrated a strong safety profile in previous clinical studies. In preclinical studies it was found to reduce tics effectively without inducing any motor side effects. Today's pharmaceutical treatments for Tourette, such as the anti-psychotic Haldol, involve multiple severe side effects.**

30 patients ranging from 12 to 45 years old will be taking part in a phase IIa proof-of-concept study at two major University Hospitals in Copenhagen - Bispebjerg and Herlev. Bispebjerg, the primary test site, will treat the majority of patients. Herlev will focus on children and teenage patients. 20 patients will receive 10 mg of Sepranolone twice weekly for 16 weeks in addition to their standard Tourette treatment, whilst 10 patients will continue on their standard Tourette treatment. Asarina expects to publish Topline results from the study in Q1 2023.

#### Sepranolone: a new approach to Tourette

Sepranolone is a highly targeted, endogenous neurosteroid developed to modulate the effects of Allopregnanolone - a key driver in the exacerbation of tics - with no off-target Central Nervous System side effects. The study is one of the first to trial such a neuroendocrinological treatment. In preclinical studies in 2019 and 2021 Sepranolone was found to reduce tics as effectively as Haldol without inducing any motor side effects (1). Sepranolone has already demonstrated an exceptionally strong safety profile (over 300 women have taken it in previous trials with no other side effects than mild and reversible local skin irritation.)

#### Tourette: the unmet need

There is a major unmet need for a safe and effective treatment for Tourette. Current treatments like haloperidol (Haldol) can involve extremely severe side effects. Whilst the majority of Tourette cases occur in children between 4 - 12 year's old, for some it persists into adulthood. 44% of parents feel that current Tourette treatments fail to adequately control their child's symptoms, and 29% of children have tried five or more different medications (2).

Tourette is also highly co-morbid with a range of other indications that may too be related to Allopregnanolone. 86% of Tourette patients have at least one additional disorder, with OCD being particularly prevalent. In March 2021, a US patent was granted for the use of Sepranolone for the treatment of OCD (3). Asarina Pharma remains committed to exploring future uses of Sepranolone for the treatment of OCD.

Peter Nordkild, CEO: “We’re proud to be working with the fantastic teams at Bispbjerg and Herlev and we are confident that their expertise and experience will contribute significantly to ensuring smooth patient selection, enrolment and engagement. As a highly targeted neurosteroid Sepranolone is a whole new, and we believe safer, approach to Tourette – and maybe other related conditions too. We’re excited to begin work on this fascinating and vital study.”

1. 2019, Behavioral fragmentation in the D1CT-7 mouse model of Tourette’s syndrome, Bortolato et al. 2021, Preliminary study of finasteride in Tourette syndrome, Moroni, Bortolato et al, 2011
2. 2018, the Tourette Association of America, Impact Survey
3. <https://news.cision.com/asarina-pharma/r/asarina-pharma-granted-us-patent-for-sepranolone-for-tourette-syndrome--ocd-and-pathological-gamblin,c3362549>

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**ABOUT ASARINA PHARMA AB**

We are a Swedish biotech company developing Sepranolone for allopregnanolone-induced stress- and compulsivity-driven disorders. Our product pipeline is built on over 40 years of research into allopregnanolone-related neurological disorders. With our new family of GAMSAs (GABA-A Modulating Steroid Antagonists) we aim to deliver a new generation of safe, efficacious drugs for neurological conditions from Tourette syndrome to Obsessive Compulsive Disorder that still lack safe, efficacious pharmaceutical treatments.