



PRESS RELEASE

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Patient recruitment completed in landmark Tourette syndrome study

(Stockholm, 14 October 2022.) **Asarina Pharma has completed the recruitment of patients to its Phase IIa clinical study in Tourette syndrome with a total of 28 patients enrolled and the last patient randomized on October 14. The dropout rate in the study remains unexpectedly low. Topline results are expected at the end of Q1 2023. The study compound, Sepranolone, is an endogenous neurosteroid, an entirely new treatment modality for Tourette. It has demonstrated a strong safety profile in multiple previous clinical studies, and reduced tics without inducing any motor side effects in previous preclinical studies.**

Enrollment of adult patients started at the Bispebjerg University Hospital in Copenhagen in February 2022, while teenage patients have been enrolled at the Danish National Center for Tourette at Herlev University Hospital since summer 2022. Until now, a total of 13 patients have completed the study. Last-patient-last-visit remains scheduled for January 2023 with topline results expected at the end of March 2023.

Low dropout rate maintained

As reported in August 2022, the Study has had an unexpectedly low dropout rate with only two patients having dropped out. In most clinical studies, the highest dropout rates tend to come from the 'active dose' group rather than from the 'control group' (those taking a placebo and/or or their usual treatment) and the study is accordingly powered to accommodate for a 40% drop out from the active group.

Peter Nordkild, CEO: "Our work with the highly experienced teams at Bispebjerg and Herlev University Hospitals is progressing very positively. I'd like to thank the two teams for their tremendous expertise in ensuring a smooth study with highly motivated patients. We look forward to sharing our topline results."

About Tourette: the unmet need

The unmet need for a safe and effective treatment is significant. A new 2022 study by the U.S. CDC (Centers for Disease Control and Prevention) in the journal *Psychiatry Research* estimated that more people than previously thought are affected by Tourette or persistent tic disorders. 1-in-50 children in the US may be affected, previous estimates were 1-in-100, and up to 450,000 U.S. children and adults suffer from Tourette according to the report. (1)

The majority of Tourette cases occur in children between 4 - 12 year's old, for some patients it persists into adulthood. Current treatments like haloperidol (Haldol) can involve extremely severe side effects. 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).

Sepranolone: a new approach to Tourette

If full clinical development and regulatory approval is successful, Sepranolone will be the first endogenous, neuroendocrinological compound used to treat Tourette – representing an entirely new treatment modality with no serious side effects. Sepranolone is highly selective and has been designed to target and modulate the effects of allopregnanolone – a powerful neurosteroid in the exacerbation of tics - with no off-target Central Nervous System side effects.

Allopregnanolone is also implicated in a wide range of other stress and compulsion disorders. Sepranolone is Asarina Pharma's synthesis of isoallopregnanolone, the body's endogenous neurohormone that modulates and inhibits the effects of allopregnanolone.

1. <https://news.cision.com/asarina-pharma/r/asarina-pharma-ab--new-us-cdc-study-suggests-prevalence-of-tourette-significantly-higher-than-previous.c3625977>
2. 2018, the Tourette Association of America, Impact Survey

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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.

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