



PRESS RELEASE

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Asarina Pharma receives approval of CTA for phase IIa Tourette study

(Stockholm, 19 May, 2021.) **Asarina Pharma's Clinical Trial Application for a phase IIa study with Sepranolone in Tourette Syndrome has been approved by the Danish Medical Agency, with the study to commence in August 2021 at two sites in Denmark.**

With Cognitive Behavioral Therapy as first-line treatment for Tourette, and many pharma treatments exhibiting severe side effects, there is a large unmet need for a safe, effective drug therapy in Tourette. In several preclinical studies, Sepranolone has demonstrated a positive tic-reducing effect on par with the antipsychotic drug, Haldol (*Haloperidol*), the most efficacious tic-reducing pharmaceutical treatment currently used for Tourette, but with none of Haldol's severe side effects.

Following the CTA approval, the study will take place at the Danish National Center for Tourette at the Herlev University Hospital, Scandinavia's largest Tourette treatment center, and Bispebjerg University Hospital, both in Copenhagen. The study will include 30 patients aged between 12 - 45 years who will receive 10 mg Sepranolone twice weekly for 12 weeks. The first patient is expected to receive the first injection in August 2021, and topline results to be published by summer 2022.

In February 2021, new preclinical data confirmed that Sepranolone suppresses tics in Tourette Syndrome (TS) in mice with no observable side-effects. The data, presented by Prof Marco Bortolato (Univ. of Utah) pointed clearly towards overproduction of the powerful neurosteroid Allopregnanolone (ALLO) in acute stress situations as a potentially crucial trigger of Tourette symptoms. Sepranolone is the first and only patented version of isoallopregnanolone, the endogenous compound that inhibits ALLO. Sepranolone's safety record is well-proven through administration of the compound to over 330 patients in three clinical studies with no serious adverse side effects recorded.

Asarina Pharma CEO Peter Nordkild: "With promising preclinical data under our belt, we are excited to start the Phase IIa study. The need for an improved pharmacological treatment for this severe disease is clear. According to a survey conducted by the Tourette Association of America, 44% of parents feel their child's Tourette symptoms are not adequately controlled by existing medication, and 29% of children and adolescents have tried five or more different medications. Sepranolone is a new opportunity in Tourette therapy. We know ALLO is implicated in Tourette, so its endogenous modulator could play a key role in helping reduce tics, ultimately helping Tourette patients regain control of their life."

For further information, please contact:

Peter Nordkild, CEO, Asarina Pharma AB

Phone: +45 25 47 16 46

E-mail: peter.nordkild@asarinapharma.com

About Asarina Pharma

We are a Swedish biotech company developing Sepranolone for allopregnanolone-related stress, menstrual and neurological disorders. Our product pipeline is built on over 40 years of research into allopregnanolone-related neurological disorders. 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 neuroendocrinological conditions.