

Asarina Pharma shows efficacy of Sepranolone in Tourette's syndrome on par with current first line treatment, but without side effects

Stockholm, April 2, 2019: **Sepranolone reduces tics in an animal model of Tourette's syndrome on par with Haldol, without inducing any motor side effects.**

The research group led by Prof. Marco Bortolato at the University of Utah has found that Sepranolone reduces the number of tic-like responses in the D1CT-7 mouse model of Tourette's syndrome (TS), with an efficacy comparable to the benchmark therapy haloperidol (Haldol).

While Asarina Pharma's main focus is on clinical development of Sepranolone for Premenstrual Dysphoric Disorder (PMDD) and Menstrual Migraine (MM), the company is exploring other diseases which are related to the stress-related effect of Allopregnanolone (ALLO).

ALLOPREGNANOLONE: KEY ROLE IN STRESS DISORDERS REVEALED

Allopregnanolone is a neurosteroid produced in the brain as part of the response to stressful situations. Previous research in the Bortolato lab has shown that, in animal models, these increases in ALLO lead to involuntary movements and other behavioral changes related to TS. These experiments suggest that, in TS patients, stress increases tic severity by promoting the production of ALLO in the brain.

Building on this evidence, Prof Bortolato's team recently tested the efficacy of Sepranolone in suppressing tic-like responses in the D1CT-7 mouse model of Tourette's Syndrome. An early experiment showed a dramatic, dose-dependent effect of Sepranolone ($p < 0.0001$). A follow-up study has revealed that Sepranolone also counters the enhancement in tics induced by ALLO ($p = 0.001$). The latest experiments demonstrated that the tic-reducing effects of Sepranolone are on par with Haldol (Haloperidol), one of the first-line pharmacological therapies approved for Tourette's syndrome, as well as Finasteride, a drug that suppresses ALLO synthesis ($p < 0.00001$).

SEPRANOLONE: HOW GREAT IS THE POTENTIAL?

Peter Nordkild, CEO: "These preclinical results in the orphan indication of Tourette's are very exciting. They show that Sepranolone can reduce the negative effects of raised Allopregnanolone concentrations not only when ALLO is produced peripherally, as is the case in PMDD or MM, but also when it is produced as a stress hormone in the brain of both genders. We believe ALLO also plays a significant role in behavioral disorders like Obsessive Compulsive Disorder and Pathological Gambling. The data confirms how broad Sepranolone's potential is."

NO SIDE EFFECTS SEEN WITH SEPRANOLONE

These findings are also exciting, as the therapies currently approved for Tourette's syndrome are associated with many side effects. Tourette's syndrome is a disease that is most prominent in males in childhood and adolescence. Haldol is an antipsychotic used as a first-line treatment for Tourette's syndrome. Treatment with Haldol is highly efficacious in reducing tic severity but is unfortunately associated with serious motor and endocrine side effects, such as parkinsonism, tardive dyskinesias, and gynecomastia.

"There is thus a great and unmet medical need for an efficacious treatment of Tourette's Syndrome that would not be associated with serious side effects" says Peter Nordkild "Asarina Pharma now has more than 200 patients that have been exposed to Sepranolone in the clinical program for PMDD and no serious side effects have been observed"

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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 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.

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