Psyadon Announces Positive Independent Review of Phase 2b Study of Ecopipam for the Treatment of Tourette's Syndrome in Children

GERMANTOWN, MD, February 3, 2016 – Psyadon Pharmaceuticals, Inc., a pharmaceutical company focused on treatments for neurology and psychiatry, announced today that the independent Drug Safety Monitoring Board (DSMB) overseeing its Phase 2b study of ecopipam in children (7-17 years) with Tourette's Syndrome has recommend the study's continuation based on its scheduled interim review of the data.

The protocol specified that when half the anticipated subjects had completed, the DSMB would meet to review the data and determine if the study should proceed as planned. The DSMB had several possible options including (1) stopping the study if there was no possibility of success; (2) stopping the study if there were sufficiently serious side effects which would outweigh any clinical benefit; (3) recommend changes to the protocol to increase the probability of a definitive outcome (e.g., increase the number of subjects to insure statistically meaningful results could be obtained); or (4) allow the study to continue without change. The DSMB recommend that the study continue and include four additional participants, for a total enrollment of 34 subjects.

"This positive interim analysis is an important milestone in the development of ecopipam. While no conclusion about the drug's activity can be inferred from the DSMB's decision, we are encouraged by their findings and highly motivated to complete this study," said Richard Chipkin, Ph.D., President and Chief Executive Officer of Psyadon.

Donald Gilbert, M.D., the study's Principal Investigator and Professor and Director of the Movement Disorder and Tourette Syndrome clinics at Cincinnati Children's Hospital Medical Center said, "The decision by the DSMB fits with what we are observing in the trial. Given the unique mechanism of action of this medication and the need for better Tourette treatments, the investigators are working to complete enrollment as soon possible."

ABOUT THE STUDY

This Phase 2b study called 'Ecopipam Treatment of Tourette's Syndrome in Subjects 7-17 Years (PSY302)', is a double-blind, randomized, placebo-controlled crossover study conducted to assess the efficacy and safety of ecopipam in children with Tourette's Syndrome.

Patients are instructed to take the study medication (either ecopipam or placebo) each evening before bedtime over a 4-week treatment period. Patients are evaluated in the clinic every other week with telephone contacts on the alternate weeks. The primary efficacy endpoint is the change in the Yale Global Tic Severity Score (YGTSS), a well-validated rating scale typically used in Tourette's Syndrome trials. The study was originally designed to enroll 30 patients, and the pre-scheduled interim analysis was performed upon completion of 15 subjects. Based on the DSMB's recommendation, the new enrollment goal is 34 subjects.

ABOUT ECOPIPAM

Ecopipam is a first-in-class drug that selectively blocks the actions of the neurotransmitter dopamine at its receptor. Dopamine receptors can be broadly classified into two families based on their structures: "D1 receptors" and "D2 receptors." Ecopipam blocks dopamine only at D1 receptors. There is evidence that overactive dopamine systems in the brain are responsible for

the symptoms of Tourette's Syndrome, and that D1 receptors play a pivotal role. In contrast, all currently marketed dopamine antagonists for the treatment of Tourette's act at D2 receptors.

ABOUT PSYADON PHARMACEUTICALS

Psyadon Pharmaceuticals is dedicated to the discovery and development of new treatments for serious neurological and psychiatric diseases. Ecopipam, our first development candidate, selectively blocks the actions of the neurotransmitter dopamine at the D1 receptor-family in the brain. This first-in-class compound has the potential to successfully help people who previously had no other therapeutic options.

For more information please visit www.psyadonrx.com.

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