Psyadon Announces Positive Interim Analysis of Phase 2 Study of Ecopipam for the Treatment of Tourette Syndrome
-- Ongoing Study Stopped Early--

GERMANTOWN, Md., July 24, 2012 – Psyadon Pharmaceuticals, Inc. announced today that its Phase 2 study of ecopipam in patients with Tourette Syndrome was stopped early when a planned interim analysis revealed a statistically significant reduction in the severity of the patients' tic symptoms. This decision was supported by both the independent Drug Safety and Monitoring Committee overseeing the study and by the external Research Committee established as part of Psyadon's partnership with the Tourette Syndrome Association (TSA) - the nation's largest patient advocacy group for this disorder.

"Stopping this study early because of positive results is an important development for Psyadon and hopefully for patients with Tourette Syndrome," said Richard Chipkin, Ph.D., president and chief executive officer of Psyadon. "We are eager to move ecopipam into the next stages of clinical development."

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 "I am encouraged by the results of this study. I believe a lot of families are looking for new treatment options and current therapies have serious side effects. Although more investigation is needed, ecopipam may represent a safer, more effective choice."

Kevin McNaught, Ph.D., vice president for medical and scientific programs at the TSA added "The TSA is proud to have helped fund this study. There haven't been any new treatments for Tourette Syndrome approved by the FDA in over twenty years. Should ecopipam's efficacy be confirmed in future trials, it would be a welcome addition to the resources available to these patients."

ABOUT THE STUDY

This Phase 2 study called 'Ecopipam Treatment of Tourette's Syndrome (PSY301)', was a multicenter, open-label, nonrandomized study conducted to assess the activity and safety of ecopipam in patients with Tourette Syndrome. Patients were instructed to take ecopipam each evening before bedtime over an 8-week treatment period at 50 mg/day for the first two weeks, and at 100 mg/day for the remaining six weeks. Patients were evaluated in the clinic every other week and with telephone contacts on the alternate weeks. The primary efficacy endpoint was the change in the Yale Global Tic Severity Score (YGTSS), a well-validated rating scale typically used in Tourette Syndrome trials. The study was designed to enroll 25-30 patients, but a pre-scheduled interim analysis was performed upon completion of 15 subjects. The patient population ranged from 19-60 years of age and had moderate to severe symptoms upon entry. Most of the patients were male (80%) which is consistent with current disease demographics.

The results showed a highly statistically significant ($p<0.001$) reduction in the Total Tic Severity Scores of the YGTSS. This effect was seen in the analysis of both patients who completed all visits (completer analysis; n=12) and all enrolled patients (intent-to-treat analysis; n=15). After

enrollment in the study was terminated on-going patients were instructed to complete all remaining visits.

Ecopipam was well tolerated in the study, showing a safety profile similar to that seen in other patient populations. This suggests that patients with Tourette Syndrome have no unique, disease-specific sensitivity to this mechanism of action. The most frequently observed side effects (rated mild to moderate) included the following (number of patients reporting): fatigue (3), nausea (3), sedation (3), headache (2), restlessness (2) and sleeplessness (2).

ABOUT ECOPIPAM

Ecopipam 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 Syndrome, and that D1 receptors play a pivotal role. In contrast, all currently marketed dopamine antagonists act at D2 receptors.

STATEMENT OF THE DRUG SAFETY MONITORING COMMITTEE (DSMC)

“Based upon a review of the data of the 15 patients enrolled in the clinical study, the DSMC has unanimously agreed that the current findings support the initiation and conduct of a controlled study in Tourette Syndrome. This decision is based on two observations. First, ecopipam's activity as measured by a decrease from baseline of 5.5 points in the primary endpoint (i.e., the Yale-Global Tic Severity Scale or YGTSS) in the 15 enrolled patients is statistically consistent with clinical improvement”. They also stated that “changes in the Clinical Global Impression (CGI) scale also support the possibility that ecopipam is producing a meaningful efficacious response”. The second basis for the DSMC’s recommendation is based on its statement that “no safety issues have occurred in the current study that would preclude further investigation in a controlled clinical trial and there are sufficient safety data from previous studies to initiate a controlled study.”

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.

ABOUT TSA

Founded in 1972, the national Tourette Syndrome Association (TSA) is celebrating its 40th year as the only national, voluntary health organization for people with Tourette Syndrome. The TSA has a three-pronged mission to identify the cause of, control the effects of, and to find a cure for Tourette Syndrome through education, research and service The TSA directs a network of 33 Chapters and more than 150 support groups across the country. http://tsa-usa.org.

CONTACT INFORMATION

FOR PSAYDON

Dr. R.E. Chipkin
info@psyadonrx.com
Psyadon Pharmaceuticals, Inc.
20451 Seneca Meadows Parkway
Germantown, MD 20876
www.psyadonrx.com

FOR TSA

Tracy Colletti-Flynn
tracy.flynn@tsa-usa.org