#### PRESS RELEASE

# PsychoGenics Inc. Announces Positive Efficacy Data in Levodopa Induced Dyskinesia in Parkinson's Patients

TARRYTOWN, N.Y., June 12, 2012 - PsychoGenics Inc. today reported positive results from a clinical study of eltoprazine in levodopa induced dyskinesia (LID) in Parkinson's disease (PD) patients. Eltoprazine met the primary objective of the study by exhibiting a statistically significant reduction in LID at the 5 mg dose (p = 0.0007) and the 7.5 mg dose (p = 0.0467), without adversely affecting levodopa efficacy. Eltoprazine was also well tolerated in this study and there were no serious adverse events.

Eltoprazine is a selective 5-HT<sub>1A</sub>/<sub>1B</sub> partial agonist. Pre-clinical data from multiple models of PD show that eltoprazine effectively reduces LID at relatively low doses. Chronic administration of eltoprazine for 45 days shows not only suppression of LID and no tolerance but also protection from development of dyskinesias. In addition, other preclinical and clinical data support the use of eltoprazine to treat the non-motor symptoms of PD such as cognitive impairment and depression.

In this double-blind, randomized, placebo-controlled, dose-finding study conducted at two sites in Sweden, twenty-two patients were given single doses of eltoprazine and placebo along with a challenge dose of levodopa at each of the 5 treatment visits and assessed for parkinsonian and dyskinesia symptoms over a period of three hours post-treatment. The assessments were video-taped and scored by two independent blinded raters.

Primary efficacy was measured using the Clinical Dyskinesia Rating Scale (CDRS) and the Unified Parkinson's Disease Rating Scale (UPDRS). Secondary endpoints included the Rush Dyskinesia Rating Scale and evaluation of the patients' mood using the Hospital Anxiety & Depression Score (HADS) and Montgomery-Asberg Depression Rating Scale (MADRS). The trial was partially supported by a grant from The Michael J. Fox Foundation for Parkinson's Research.

Emer Leahy, Ph.D., President & CEO of PsychoGenics said "The results of this trial are compelling and show that eltoprazine has the potential to address a critical unmet need in Parkinson's disease. We are happy to have collaborated with Dr. Andres Bjorklund, a renowned expert in the LID field and a member of the Scientific Advisory Board of The Michael J. Fox Foundation. We are also very appreciative of the support from the Michael J. Fox Foundation. With these promising positive data we now intend to progress eltoprazine to market as quickly as possible with support from a partner".

"Dyskinesia is a top priority for the Foundation because of its impact on the quality of life of people living with Parkinson's disease," said Todd Sherer, PhD, CEO of The Michael J. Fox Foundation. "The results presented by PsychoGenics and Dr. Bjorklund show early promise in finding a potential treatment for dyskinesia, and we look forward to working with this team to drive their program forward."



Anders Bjorklund, MD, Ph.D., Wallenberg Neuroscience Center, University of Lund, Sweden said. "There is extensive evidence for the role of serotonin neurons in the induction and maintenance of LID. We have shown that 5-HT<sub>1A</sub> and 5-HT<sub>1B</sub> agonists have a synergistic effect in suppressing LID in preclinical models. Doses of 5-HT<sub>1A</sub> and 5-HT<sub>1B</sub> receptor agonists, which individually produced a reduction in dyskinesia, were able to further significantly reduce dyskinesia severity when administered in combination, without affecting the anti-parkinsonian properties of levodopa. The results of this clinical are encouraging and in line with the data generated in animal models."

### About Eltoprazine and its role in dyskinesias

Serotonin neurons are known to be able to convert levodopa to dopamine, as well as store and release dopamine in an activity-dependent manner. In advanced patients, where the dopamine terminals have largely degenerated, serotonin terminals are considered a major source of dopamine release. However, serotonin neurons lack feedback control mechanisms for the release of dopamine, such as the  $D_2$  autoreceptor and the dopamine transporter, which normally regulate the synaptic level of dopamine within a physiological range. Administration of levodopa, therefore generates high swings in synaptic dopamine, causing pulsatile stimulation of post-synaptic dopamine receptors, and the appearance of dyskinesia. Preclinical research has shown that removal of the serotonin innervation or activation of pre-synaptic receptors of the serotonin neurons by a combination of 5-HT $_{1A}$  and 5-HT $_{1B}$  receptor agonists produces a suppression of LID. On the basis of these findings it was logical to test eltoprazine in a LID clinical trial.

Eltoprazine is a selective 5-HT $_{1A}/_{1B}$  partial agonist. Clinical data also shows statistically significant effects in adult ADHD patients. A study supported by the National Institutes of Mental Health (NIMH) in Cognitive Impairment Associated with Schizophrenia (CIAS) is ongoing.

## **About PsychoGenics Inc.**

PsychoGenics is a preclinical contract research organization that provides a full complement of partnered drug discovery capabilities with a focus on psychiatric, cognitive and neurodegenerative disorders, pain, inflammation, spinal cord and traumatic brain injury. PsychoGenics transforms drug discovery by combining expertise in behavioral neurobiology with the power of bioinformatics in conjunction with proprietary, high-throughput behavioral testing platforms that rapidly screen compound libraries for CNS activity. PsychoGenics works with pharmaceutical and biotechnology companies, academic institutions, and not-for-profit research foundations to help discover treatments for major neurological and psychiatric disorders. For more information about PsychoGenics please visit <a href="https://www.psychogenics.com">www.psychogenics.com</a>.

#### About The Michael J. Fox Foundation for Parkinson's Research

As the world's largest private funder of Parkinson's research, The Michael J. Fox Foundation is dedicated to accelerating a cure for Parkinson's disease and improved therapies for those living with the condition today. The Foundation pursues its goals through an aggressively funded, highly targeted research program coupled with active global engagement of scientists, Parkinson's patients, business leaders, clinical trial participants, donors and volunteers. In addition to funding more than \$289 million in research to date, the Foundation has fundamentally altered the trajectory of progress toward a cure. Operating at the hub of worldwide Parkinson's research, the Foundation forges groundbreaking collaborations with industry leaders, academic scientists and government research funders; increases the flow of participants into Parkinson's disease clinical trials with its online tool, Fox Trial Finder; promotes Parkinson's awareness through high-profile advocacy, events and outreach; and coordinates the grassroots involvement of thousands of Team Fox members around the world. Now through December 31, 2012, all new and increased giving to The Michael J. Fox Foundation, as well as gifts from donors who have not given since 2010 or earlier, will be matched



on a dollar-for-dollar basis with the \$50-million Brin Wojcicki Challenge, launched by Sergey Brin and Anne Wojcicki. Please visit: <a href="www.michaeljfox.org">www.michaeljfox.org</a>; <a href="www.michaeljfox.org">www.facebook.com/michaeljfoxfoundation</a> for more information.

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