

Intra-Cellular Therapies Announces Positive Results With Iti-002 in Pre-Clinical Models of Parkinson's Disease.

Intra-Cellular Therapies, Inc. today announced results from studies demonstrating the anti-Parkinson and other beneficial effects of ITI-002 (IC200214), the Company's novel and selective phosphodiesterase type I (PDE1) inhibitor.

Intra-Cellular Therapies presented preclinical data at the 2nd World Parkinson Congress held in Glasgow, Scotland, demonstrating ITI-002 was effective in improving motor and non-motor behaviors relevant to the treatment of Parkinson's disease. In well-established pre-clinical models of PD, ITI-002 was shown to restore normal motor function when given in combination with L-DOPA; ITI-002 increased the effectiveness of a sub-threshold and a sub-maximal dose of L-DOPA when the compounds were co-administered in unilaterally 6-hydroxy dopamine-lesioned or reserpine-treated mice. This combination resulted in a full restoration of the affected limb use and a re-establishment of normal mobility. ITI-002 also reversed the akinesia and catalepsy induced by the dopamine receptor antagonist haloperidol. In other pre-clinical models, ITI-002 was shown to improve cognitive performance and to increase daytime wakefulness without causing psychomotor stimulation.

"We are pleased to have demonstrated the ability of ITI-002 to improve motor and non-motor behaviors in pre-clinical models relevant to Parkinson's disease. These data suggest ITI-002 may be useful in prolonging the effectiveness and lowering the doses of dopamine replacement therapies, thereby providing for full restoration of motor function without causing troubling side effects in patients with Parkinson's Disease," stated Sharon Mates, Chief Executive Officer of Intra-Cellular Therapies. "Since ITI-002 acts by enhancing intra-cellular dopamine signaling, ITI-002 also may be useful as a stand-alone treatment early in this disease when residual dopamine is still present. In addition, patients with Parkinson's disease often suffer co-morbidly with dementia and excessive day time sleepiness. We believe that ITI-002 will be uniquely effective in treating these non-motor complications that are associated with Parkinson's disease."

ABOUT ITI-002

ITI-002 is a unique, orally available, investigational drug being developed for the treatment of motor and non-motor impairments accompanying Parkinson's disease and other neurologic and neuropsychiatric disorders, including schizophrenia and Alzheimer's disease. ITI-002 potently inhibits the PDE1 enzyme in a competitive manner with sub-nanomolar affinity for this subfamily. This compound is very selective for the PDE1 subfamily relative to other PDE subfamilies. ITI-002 has no significant off target activities at other enzymes, receptor or ion channels.

PDE Type I - PDE enzymes hydrolyze and inactivate cyclic nucleotides (cAMP and cGMP) in the brain. Eleven classes of PDE enzymes with distinct tissue distributions, cyclic nucleotide selectivity, and regulatory factors are known. The PDE1 family of enzymes, including PDE1A, PDE1B, and PDE1C isoforms, are calcium / calmodulin-dependent, dual-function (cAMP/cGMP) PDEs that are expressed at high levels in mammalian brain. This enzyme subfamily has little influence on basal nucleotide activity and only becomes active under stimulated conditions. This "on demand" character distinguishes PDE1 from all other PDE family members. PDE1 is enriched in the striatal medium spiny neurons that lose dopamine input in Parkinson's disease and controls the responsiveness of striatal neurons to dopamine. Intra-Cellular Therapies has shown that orally available, small molecule inhibitors of PDE1 restore dopamine signaling in striatal neurons and potentiate the level of motor correction in Parkinson's disease.

About Parkinson's Disease - Parkinson's disease is a progressive, neurodegenerative disease. The prevalence of Parkinson's disease increases with age, reaching 4% of the population over 80. Mean age of onset is around 60 years, although in 5-10% of cases the onset is earlier and occurs between the ages of 20 and 50. Primary symptoms include decreased motor function caused by appearance of tremor, rigidity, bradykinesia, and postural instability. Many patients co-morbidly exhibit impaired cognitive function, depression and excessive day time sleepiness. Dopamine replacement therapies, such as L-DOPA, are the current treatments of choice. However, with time on drug and with disease progression, these drug therapies often lose effectiveness and can cause unwanted side effects such as dyskinesias and hallucinosis.

ABOUT INTRA-CELLULAR THERAPIES

Intra-Cellular Therapies, Inc. (ITI) is a biopharmaceutical company developing novel drugs for the treatment of diseases and disorders of the Central Nervous System (CNS). Building on the science generated from the Nobel Prize winning laboratory of Dr. Paul Greengard at The Rockefeller University, the Company develops compounds that have the potential to treat a wide range of diseases associated with the CNS, including schizophrenia, sleep disorders, Parkinson's disease and Alzheimer's

disease, cognitive deficits in schizophrenia, depression and female sexual dysfunction, and other disorders pertaining to Women's Health. To aid in the development process, ITI incorporates its CNSProfile™, a statef-the-art platform that allows the Company to choose compounds with the strongest potential to succeed in these difficult to treat diseases.

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