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Intra-Cellular Therapies Announces Completion of Phase I Single Rising Dose Trial of First-In-Class Selective Phosphodiesterase 1 (PDE1) Inhibitor and Reports Top-Line Safety and Pharmacokinetic Findings.

Intra-Cellular Therapies, Inc. ("ITI") today announced the completion of a Phase I single rising dose study of its phosphodiesterase 1 (PDE1) inhibitor, ITI-214. ITI-214, a novel, first-in-class selective PDE1 inhibitor, was discovered by ITI and is in development under an exclusive collaboration with Takeda Pharmaceutical Company Limited for the treatment of Cognitive Impairment Associated with Schizophrenia (CIAS).

The primary objectives of the Phase I study were to determine the safety, tolerability and pharmacokinetic profile of single oral doses of ITI-214 in healthy volunteers. The study was conducted as a randomized, double-blind, placebo-controlled study in 70 subjects. The results indicated that ITI-214 was safe and well-tolerated across a broad range of single oral doses. Moreover, ITI-214 demonstrates a favorable pharmacokinetic profile consistent with once-a-day dosing. The study represents a significant milestone as it is the first demonstration of the safety of a PDE1 inhibitor in a Phase 1 clinical trial.

"We are pleased with the advancement of ITI-214 in clinical development," stated Sharon Mates, Ph.D., Chairman and Chief Executive Officer of Intra-Cellular Therapies. "The data obtained for ITI-214 support its continued development for the treatment of Cognitive Impairment Associated with Schizophrenia and other neuropsychiatric and neurological disorders."

About Schizophrenia

Schizophrenia is a major neuropsychiatric disorder that affects over one percent of the world population with an illness that begins in late adolescence and lasts a lifetime. Its best known symptoms are "positive symptoms", which include hallucinations and delusions; but other mental functions are also affected, including social and motivational skills ("negative symptoms") and cognitive behaviors, like inattention and poor memory. Current antipsychotics are effective primarily on reducing positive symptoms but are largely ineffective at reducing negative and cognitive symptoms. The medical need in this disease area is enormous.

About PDE1 Inhibitors

These compounds are unique, orally available, investigational drugs being developed for the treatment of cognitive impairments accompanying schizophrenia and other neurological and neuropsychiatric disorders, including Alzheimer's disease, Attention Deficit Hyperactivity Disorder and Parkinson's disease. These compounds may also have the potential to improve motor dysfunction associated with these disorders. These compounds are very selective for the PDE1 subfamily relative to other PDE subfamilies. They have no known significant off target activities at other enzymes, receptors or ion channels.

About Intra-Cellular Therapies, Inc.

Intra-Cellular Therapies, Inc. (ITI) is a biopharmaceutical company that is developing novel drugs for the treatment of diseases and disorders of the Central Nervous System (CNS). The Company was formed in 2002 to exploit intracellular signaling pathways of the brain in its efforts to develop novel CNS therapeutics. The Company's initial efforts were built on the insights generated from the Nobel Prize winning science of Dr. Paul Greengard at The Rockefeller University, the scientific founder of ITI. Using novel technologies developed at ITI, the Company has developed a pipeline of drugs that have the potential to treat a wide range of diseases associated with the CNS. Additional information about ITI is available through its corporate website, www.intracellulartherapies.com.

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