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Intra-Cellular Therapies Presents Data on its Schizophrenia and Cognition in Schizophrenia Programs at the 14th Biennial Winter Workshop on Schizophrenia and Bipolar Disorders.

Intra-Cellular Therapies, Inc. (ITI), announced the presentation of preclinical data on ITI-007, its first-in-class dual 5HT2A receptor anatagonist/dopamine receptor phosphoprotein modulator (DPPM) for the treatment of schizophrenia, and ITI-002, ITI's family of compounds that inhibit a novel intracellular target for the treatment of cognitive dysfunction in schizophrenia. Data characterizing the pharmacological profile of these drug candidates were highlighted in an oral presentation given last week at the 14th Biennial Winter Workshop on Schizophrenia and Bipolar Disorders. ITI-007 is currently in Phase I clinical trials for the treatment of schizophrenia.

"We believe the novel pharmacological properties of ITI-007 may provide new treatment alternatives with significant safety and patient compliance-related advantages over currently available therapies for the treatment of schizophrenia," said Sharon Mates, Ph.D., Chairman and Chief Executive Officer of Intra-Cellular Therapies. "In addition we are developing ITI-002 to treat cognitive dysfunction in schizophrenia which remains an important quality of life issue for individuals with schizophrenia and is not addressed by current medications."

ITI-007 STUDY RESULTS

In vitro, ITI-007 was shown to be a potent, sub-nanomolar, antagonist at 5HT2A receptors with a 60-fold higher affinity for 5HT2A receptors over D2 receptors. In vivo, ITI-007 produced an intracellular protein phosphorylation pattern consistent with the activity of a partial agonist at pre-synaptic D2 receptors. This pre-synaptic partial-agonist activity preserves normal dopamine metabolism rather than causing a dramatic increase as seen with other antipsychotic therapies. Behaviorally, ITI-007 inhibited serotonin induced head twitches. Additionally, ITI-007 was shown to have an affinity for the serotonin reuptake site, an activity that potentially may be beneficial in treating affective disorders.

ITI's CNSProfile™ has shown that, unlike some atypical antipsychotics, ITI-007 does not exhibit significant potency for a variety of other targets that have been implicated in a range of dose-limiting side effects of antipsychotic drugs. ITI-007 does not interact with muscarinic or histaminergic receptors and has a reduced affinity for adrenergic receptors relative to other antipsychotic drugs and relative to its potency at 5HT 2A receptors.

ITI-002 STUDY RESULTS

ITI-002 was shown to be an orally active and a potent inhibitor of a novel intracellular target and was designed to amplify but not supplant ongoing activity of D1 receptive neurons, primarily in the prefrontal cortex. In behavioral studies ITI-002 displayed acute and chronic activity as a cognitive enhancing agent in rodent models. ITI-002 has been shown to be safe in all preliminary evaluations and is advancing to pre-clinical development. It is envisioned that activation of D1 activity will improve the cognitive deficits seen in patients with schizophrenia.

ABOUT ITI-007

ITI-007 is an orally available compound that combines potent 5HT2A receptor antagonism with cell-type-specific modulation of phosphoprotein pathways downstream of dopamine receptors. As a dopamine receptor protein phosphorylation modulator (DPPM), ITI-007 has dual properties; it acts as a post-synaptic antagonist and as a pre-synaptic partial agonist. The combination of ITI-007's high-potency blockade of 5HT2A receptors and unique dopamine receptor activity will make it possible for the first time, to select a clinical dose capable of saturating 5HT2A receptors while permitting the "dialing in" of an optimal amount of dopamine receptor modulation by simple dose adjustments using a single drug. The ability to optimize the level of dopamine receptor modulation holds promise for the reduction of psychotic symptoms without incurring high levels of dopamine antagonism that cause motor disturbances and other deleterious side effects. In addition, the wide separation of affinity at 5HT2A and D2 receptors may allow for administration of the appropriate amount of dopamine modulation for antipsychotic maintenance therapy and the treatment of bipolar disorders.

ITI-007 has a much lower propensity than several currently marketed antipsychotic drugs to interact with receptors that mediate deleterious cardiovascular events, sedation, and rapid and significant weight gain.

ABOUT ITI-002

ITI-002 refers to a novel family of compounds that are potent inhibitors aimed at potentiating the dopamine signal in dopamine

target neurons. The target enzyme regulated by ITI-002 is part of the D1 dopamine receptor signaling pathway, which plays a critical role in working memory processes that are involved in maintaining and manipulating information in the brain. These processes guide higher-level behavior and high-level cognition, such as language, problem solving and reasoning. Preclinical data suggest that these compounds may have utility in treating disorders, as widely diverse as cognitive dysfunction in schizophrenia, attention deficit hyperactivity disorder and the cognitive deficits arising from Parkinson's and Alzheimer's diseases. ITI-002 also may be useful in treating the motor deficits that are associated with Parkinson's disease.

ABOUT SCHIZOPHRENIA

Schizophrenia is a major neuropsychiatric disorder that affects over 1% 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 leave negative and cognitive symptoms untouched. Not only are current drugs incompletely active, but they also have limiting side effects, including troublesome actions on motor function, weight gain, and metabolic symptoms (diabetes and hyperlipidemia), along with sedation, constipation, dizziness, and loss of bladder control. Few people with schizophrenia regain normal psychosocial function; the medical need in this disease area is enormous.

CNSProfile™

The Company has developed a state-of-the-art technology platform, called CNSProfile™ that is capable of generating a uniqu molecular signature for drug compounds. Specifically, CNSProfile™ measures the levels of phosphoproteins, proteins chemically linked at specific sites to phosphates. This profile provides the Company with a proprietary and unique window into the intracellular action of CNS drugs or drug candidates. Intra-Cellular Therapies uses this platform in its drug discovery and development efforts of proprietary compounds and also to evaluate in-licensing opportunities.

ABOUT INTRA-CELLULAR THERAPIES

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). 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 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, the Company incorporates its CNSProfile™, a state-of-the-art platform that allows ITI to choose compounds with the strongest potential to succeed in these difficult to treat diseases.

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