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Intra-Cellular Therapies Announces the Discovery of Potent Antidepressant Activity in ITI-007

Intra-Cellular Therapies, Inc., today announced additional preclinical data from its ongoing development programs for ITI-007, the Company's first-in-class dual 5HT2A receptor antagonist/dopamine receptor phosphoprotein modulator (DPPM), and ITI-722, a low-dose formulation of ITI-007, which are in development for schizophrenia and sleep disorders, respectively. These new data demonstrate ITI-007 has preclinical activity both in vitro and in vivo as an antidepressant.

ITI-007 acts as a potent inhibitor of the serotonin transporter (SERT), a major target for most antidepressant drugs. To examine whether this in vitro activity could be predictive of behavioral activity in vivo, the antidepressant effect of ITI-007 was investigated using an animal model of depression involving social stress. Repeated treatment of ITI-007 improved performance in this animal model, consistent with antidepressant-like efficacy. The combined actions of ITI-007 as a SERT inhibitor, a 5HT2A receptor antagonist, and a DPPM may provide a unique, antidepressant drug with a more optimal profile, including a lack of sexual side effects common to other antidepressant drugs.

"These studies demonstrate ITI-007 may have antidepressant activity in addition to its potential in treating sleep maintenance insomnia and psychosis in patients," stated Sharon Mates, Ph.D., Chairman and Chief Executive Officer of Intra-Cellular Therapies. "We believe ITI-007 represents a unique compound that may have broad use in treating many neuropsychiatric and neurodegenerative disorders where sleep problems, depression, or psychosis are prominent symptoms, including schizophrenia, affective disorders, and Parkinson's disease."

ABOUT ITI-007

ITI-007 is an orally available compound which combines potent 5HT2A receptor antagonism with cell-type-specific modulation of phosphoprotein pathways downstream of dopamine receptors. As a dopamine receptor phosphoprotein 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. 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 in the treatment of bipolar disorders. ITI-007 also has nanomolar affinity for the serotonin transporter (SERT). ITI-007 has a much lower propensity than several currently marketed antipsychotic drugs to bind receptors that mediate deleterious cardiovascular events, sedation and rapid and significant weight gain.

ABOUT ITI-722

A low-dose formulation of ITI-007, called ITI-722, is being developed simultaneously for the treatment of sleep maintenance insomnia in the general population. Due to the unique separation of D2 and 5HT2A receptor affinities, at low doses, ITI-722 acts primarily as a 5HT2A receptor antagonist. Additionally, its profile suggests the compound may be appropriate for the treatment of sleep disorders that accompany neurodegenerative disorders, such as Parkinson's disease.

ABOUT DEPRESSION

Depression is a common psychiatric disorder affecting approximately 20 million people in the United States. It is characterized by a pervasive low mood, loss of interest in usual activities and diminished ability to experience pleasure. Although the term "depression" is commonly used to describe a temporarily depressed mood when one "feels blue," clinical depression is a serious and often disabling condition that can significantly affect a person's work, family and school life, sleeping and eating habits, general health, and ability to enjoy life. Having depression is also a major risk factor for suicide; in addition, people with depression suffer from higher mortality from other causes. Moreover, depression is a common co- morbid diagnosis in schizophrenia, being present in over 30% of people with schizophrenia in many studies.

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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