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# Intra-Cellular Therapies Initiates Phase I Clinical Program for Schizophrenia and Sleep Maintenance Disorders.

## ITI-007 - A Novel, First-in-Class Dual 5HT2A Receptor Antagonist/Dopamine Phosphoprotein Modulator (DPPM) for Schizophrenia and ITI-722- A 5HT2A Receptor Antagonist for Sleep Maintenance Disorders

NEW YORK, NY, JUNE 21, 2007 -- Intra-Cellular Therapies, Inc., today announced it has initiated Phase I clinical trials for ITI-007, the Company's first-in-class dual 5HT2A receptor antagonist/dopamine receptor phosphoprotein modulator (DPPM) for the treatment of schizophrenia, and ITI-722, a low dose formulation of ITI-007 with selective 5HT2A receptor antagonist properties for the treatment of sleep maintenance insomnia. The primary objective of these studies is to determine the pharmacokinetics, safety, and maximum tolerated dose (MTD) of ITI-007 in healthy volunteers as a prelude to efficacy studies for the treatment of acute psychotic symptoms in patients with schizophrenia and for the treatment of sleep maintenance insomnia. Both ITI-007 and ITI-722 are part of a large portfolio of compounds originally licensed from Bristol Myers Squibb Company (BMY).

"We are pleased ITI-007 and ITI-722 are moving forward into clinical studies. These programs have a novel combination of pharmacologic properties, that have the potential to define the future of antipsychotic drug therapy and treatment of sleep maintenance disorders," stated Sharon Mates, Ph.D., Chairman and Chief Executive Officer of Intra-Cellular Therapies. "We believe this approach may have significant treatment advantages over currently marketed drugs and also should be free of many unwanted side effects associated with current therapies."

**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 and the treatment of bipolar disorders.

ITI's technology platform CNSProfile™ has revealed ITI-007 is a novel phosphoprotein modulator, selectively blocking overactive dopamine responsive phosphoprotein pathways without stimulating compensatory dopamine synthesis, demonstrating ITI-007's unique, partial agonist-like properties. Standard pharmacologic assays have confirmed ITI-007's partial agonist properties at the presynaptic dopamine D2 receptor and confirmed serotonin transporter antagonist activity which may be of added benefit to patients with schizoaffective disorder and other diseases associated with mood alterations. 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 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.

**About Sleep Maintenance Disorders**

From nightmares to insomnia to sleep apnea, sleep disorders disrupt the sleep of millions of people all over the world. In particular, about 20% to 30% of the U.S. population complains of waking too early at least a few times a week, a symptom of sleep maintenance insomnia which is characterized by symptoms which include waking up frequently during the night with difficulty returning to sleep, waking up at early hours and unrefreshing sleep. The majority of sleep complaints are related to sleep maintenance insomnia rather than sleep initiation or difficulty in falling asleep. However, there are no drugs currently approved in the U.S. that only address sleep maintenance insomnia. Furthermore, current sleep medications typically induce sedation and result in significant increases in daytime sleepiness that impairs the quality of life in these patients. There is, therefore, a significant need for sleep medications that improve sleep quality without residual daytime sedation.

**CNSProfile™**

The Company has developed a state-of-the-art technology platform, called CNSProfile™ that is capable of generating a unique 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 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. 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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