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Intra-Cellular Therapies Announces Successful Outcome of a Phase II Clinical Trial With Iti-007 in Patients With Sleep Maintenance Insomnia

"TRIAL CONCLUDED EARLY DUE TO ACHIEVEMENT OF STATISTICAL SIGNIFICANCE DEMONSTRATED AT THE PRIMARY ENDPOINT"

Intra-Cellular Therapies, Inc. today announced successful top-line efficacy results for ITI-007 from a Phase II trial in Insomnia characterized by difficulty in maintaining sleep, also known as sleep maintenance insomnia (SMI). These data demonstrate that ITI-007 is safe and well-tolerated and demonstrate efficacy in reducing sleep disturbances. ITI-007 is the Company's first-in-class dual 5HT2A receptor antagonist/dopamine receptor phosphoprotein modulator (DPPM) for the treatment of schizophrenia. A low dose formulation of ITI-007 (formerly referred to as ITI-722) whose actions are predominantly mediated by 5HT2A receptor antagonism is being developed for the treatment of SMI.

“The results that we have analyzed to date from this study are encouraging. Based on the robustness of the effects observed at the interim analysis, and after extensive consultation with outside sleep experts, we have decided to conclude this phase of the trial for ITI-007 ahead of time with only half of the planned enrollment,” stated Sharon Mates, Chief Executive Officer of Intra-Cellular Therapies. “We are now moving forward with an analysis of all other outcome measures and look forward to the continued development of ITI-007 in patients who suffer from Primary or comorbid Insomnia. Furthermore, these data serve to demonstrate the potential of ITI-007 as a next generation antipsychotic and treatment for sleep disorders in various patient populations including depression, bipolar disorder, Alzheimer's disease, mild cognitive impairment and other neuropsychiatric and neurodegenerative disorders where there is clear unmet medical need.”

SUMMARY OF PHASE II SMI RESULTS

ITI-007 is an orally available drug candidate being evaluated at low doses in patients with SMI. An interim analysis (N=18 patients) was conducted for key endpoints half-way through the initially planned enrollment of this study. When compared to placebo, patients treated with ITI-007 demonstrated dose-dependent increases in slow wave sleep (SWS) and robust decreases in wake after sleep onset (WASO) as measured by polysomnography (PSG). These outcomes met the predefined objectives of the study.

This Phase II trial was a double-blind, placebo controlled, 4-way crossover design comparing placebo to 3 doses of ITI-007 in patients with SMI. Analysis of key therapeutic endpoints in this study indicated that ITI-007 dose-dependently and significantly increased SWS (p=0.002) and decreased WASO (p=0.032) over a wide range of doses. Importantly this robust decrease in WASO was reflected in increases in total sleep time. The effects on sleep persisted throughout the night. Doses of ITI-007 were safe and well-tolerated, and were not associated with any safety concerns.

PHASE II RESULTS FOR ITI-007

The effects of ITI-007 on WASO and SWS are likely due to the ability of ITI-007 to potently antagonize 5HT2A receptors at low doses (as low as 1 mg) and due to the expanded pharmacological effects that emerge as higher doses were tested. The magnitude of these effects is larger than that seen with other drugs of this class and may be attributed to additional beneficial pharmacology that emerges at the higher doses tested. At the highest dose tested (10 mg) we expect to have full occupancy of 5HT2A receptors while adding incremental amounts of D2 receptor and serotonin reuptake transporter (SERT) occupancy. This has been confirmed in an ongoing human Positron Emission Tomography (PET) study where we have demonstrated that this dose is associated with measurable brain dopamine D2 receptor occupancy (see below).

These robust decreases in WASO suggest that ITI-007 will have utility in treating not only SMI, but also other disorders

associated with fragmented sleep including many neuropsychiatric (e.g. major depression, bipolar disorder, PTSD, mild cognitive impairment and schizophrenia) and neurological diseases (e.g. Parkinson's and Alzheimer's diseases). Furthermore, increases in SWS are thought to be a biomarker for 5HT2A receptor occupancy and as predicted from preclinical data, low doses of ITI-007 appear to occupy 5HT2A brain receptors and increase SWS. These data provide a firm base for projecting the expected efficacious dose range for ITI-007 as this drug is advanced in future studies for several indications, including SMI, sleep disorders in depression and other psychiatric disorders, and schizophrenia.

HIGHLIGHTS FROM PHASE I STUDIES

In separate Phase I single and multiple dose studies, ITI-007 was found to be safe and generally well-tolerated and was associated with dose proportional increases in plasma drug level. In ongoing human PET studies using a dose range studied in the Phase I and II studies (1-30 mg), ITI-007 was shown to produce dose-dependent and therapeutically relevant increases in dopamine D2 receptor occupancy in human brain. These Phase I studies indicate this drug is safe and generally well-tolerated. To date more than 75 people have been exposed to ITI-007.

ABOUT SLEEP MAINTENANCE DISORDERS

From 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 up frequently during the night or too early several times a week, symptoms of SMI that are characterized by difficulty staying asleep and unrefreshing sleep. In many populations (e.g. the elderly) the majority of sleep complaints are related to SMI rather than sleep initiation or difficulty in falling asleep. In addition, this type of sleep disruption is common in patients with depression, bipolar disorder and other mood disorders, Alzheimer's disease (AD) and neurological disorders. For example, sleep disturbances in patients with Alzheimer's disease is one of the primary reasons that persons with AD are institutionalized. There is a significant need for sleep medications that improve sleep quality in patients with neuropsychiatric and neurologic disorders and comorbid sleep disorders.

ABOUT ITI-007

ITI-007 is the Company's first-in-class dual 5HT2A receptor antagonist/dopamine receptor phosphoprotein modulator (DPPM) for the treatment of schizophrenia. 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 should allow a personalized approach to patient treatment for schizophrenia by making 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 low propensity to interact with receptors that mediate deleterious cardiovascular events, sedation and rapid and significant weight gain.

Low dose ITI-007 (formerly referred to as ITI-722) is a highly potent 5HT2A antagonist for the treatment of sleep maintenance insomnia. Preclinical data have shown that ITI-007 is sleep promoting without having sedative properties and should not exhibit sedative side effects during the night (e.g. falls, amnesia) or next day hangover effects that are commonly associated with other sleep medications. ITI-007 is expected to have a strong safety profile with no addiction liability. This compound is being evaluated for the treatment of sleep disorders in various patient populations with sleep maintenance problems and in other sleep disorders such as sleep disorders in depression, other mood disorders, Alzheimer's disease and schizophrenia.

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 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 state-of-the-art platform that allows the Company to choose compounds with the strongest potential to succeed in these difficult to treat diseases.

ABOUT CNSProfile™

Intra-Cellular Therapies has developed a state-of-the-art technology platform, called CNSProfile TM , that is capable of generating a unique molecular signature for drug compounds. Specifically, CNSProfile TM 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.

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