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Intra-Cellular Therapies Initiates Phase 2 Clinical Trial for Sleep Maintenance Insomnia.

Intra-Cellular Therapies, Inc. (ITI), today announced it has initiated a sleep maintenance insomnia (SMI) Phase 2 clinical study using its drug candidate ITI-722. ITI-722 acts predominantly as a selective 5-HT2A receptor antagonist and represents an important new approach to the treatment of SMI. Because of its novel separation of 5-HT2A and dopamine receptor modulatory activities, ITI believes, ITI-722 can be used not only to treat SMI but it may be highly appropriate for the treatment of sleep disorders that accompany neurodegenerative disorders, including Parkinson's disease and other psychiatric disorders.

"The progression of ITI-722 into Phase 2 for SMI represents the advancement of this important new class of therapeutics," stated Sharon Mates, Ph.D., Chairman and Chief Executive Officer of Intra-Cellular Therapies. "This drug candidate has therapeutic potential to treat SMI in the general population, and in other patient populations who have been underserved, particularly peri-and post-menopausal women, and in other disorders where insomnia is a problem, including osteoarthritis, depression, Parkinson's disease and other neurologic and psychiatric disorders." The Phase 2 program is a multi-center, randomized, double-blind placebo-controlled study inpatients with SMI. The primary endpoint is an assessment of objective slow wave sleep using polysomnography (PSG). Secondary endpoints include other objective and subjective measures of SMI and sleep efficiency. Additionally, the study will make an assessment regarding next-day cognitive performance.

ITI-722 is a low-dose formulation of ITI-007, ITI's first-in-class 5-HT2A antagonist/ dopamine receptor protein phosphorylation modulator (DPPM), presently in clinical trials for the treatment of schizophrenia.

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 several times a week, a symptom of sleep maintenance insomnia (SMI) that is characterized by symptoms that 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 SMI rather than sleep initiation or difficulty in falling asleep. However, there are no drugs currently approved in the U.S. that address only SMI. Furthermore, current sleep medications typically induce sedation and result in significant increases in daytime sleepiness that impairs quality of life in these patients. There is, therefore, a significant need for sleep medications that improve sleep quality without next-day hangover effects.

ABOUT ITI-722

ITI-722 is a highly potent 5HT2A antagonist for the treatment of sleep maintenance insomnia. Preclinical data has shown that ITI-722 is not sedating and should not exibit next day hangover effects that are commonly associated with other sleep medications. ITI-722 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 where staying asleep affects the quality of life, including nocturnal awakenings related to osteoarthritic pain, hot flashes in post menopausal women and many psychiatric and neurodegenerative diseases.

ABOUT CNSProfile™

The Company has developed a state-of-the-art technology platform, called CNSProfileTM, that is capable of generating a unique molecular signature for drug compounds. Specifically, CNSProfileTM 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 ITI-007

ITI-007 is the Company's first-in-class dual 5-HT2A receptor antagonist/dopamine receptor protein phosphorylation 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 5-HT2A 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 5-HT2A 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.

ITI-007 currently is being evaluated in several Phase I studies examining safety and tolerability, and 5HT2A and D2 occupancy in normal healthy volunteers at doses that interact with both 5-HT2A and dopamine receptors.

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.

For further information please contact:

Intra-Cellular Therapies, Inc.
Contact: Allen A. Fienberg, Ph.D
Vice President, Business Development
212-923-3344

Burns McClellan, Inc.
Juliane Snowden (Investors)
Kathy L. Nugent, Ph.D. (Media)
212-213-0006