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Intra-Cellular Therapies Reports Positive Final Results of a Phase II Clinical Trial With ITI-007 in Patients with Sleep Maintenance Insomnia.

"TRIAL MEETS PRIMARY AND KEY SECONDARY ENDPOINTS"

Intra-Cellular Therapies, Inc. today announced the final results from the ITI-007 Phase II trial in patients with Sleep Maintenance Insomnia (SMI). In this study, ITI-007 significantly and dose-dependently increased slow wave sleep and decreased the duration of wake after sleep onset as measured by polysomnography (PSG), meeting the prespecified primary and key secondary endpoints of the trial. ITI-007 also increased total sleep time and sleep efficiency. PSG improvements such as increased total sleep time and slow wave sleep are associated with reports of improved sleep quality. Improvement in these sleep parameters is driven by the unique pharmacology of ITI-007 that can act simultaneously as a 5HT2A receptor antagonist, dopamine receptor phosphoprotein modulator (DPPM), and inhibitor of serotonin reuptake. These additional actions clearly differentiate ITI-007 from other sleep modulating drugs. The present Phase II data suggest the beneficial effects on sleep are a result of ITI-007's distinctive neuropharmacological mechanisms beyond simple 5HT2A receptor antagonism. As such, ITI-007 represents a novel approach for the treatment of insomnia characterized by difficulty in staying asleep, as well as for the treatment of insomnia related to psychiatric and neurologic disorders. These clinical results will be presented at a major scientific meeting in June.

“We are excited to have demonstrated ITI-007's ability to produce such robust improvements on sleep quality,” stated Sharon Mates, Chief Executive Officer of Intra-Cellular Therapies. “We believe that the positive effects on sleep in this study are a result of ITI-007's unique pharmacological profile that clearly differentiate it from currently available sleep inducing or sleep maintaining drugs. These data set the stage for further investigation of ITI-007's ability to improve sleep in a wide variety of diseases where sleep improvement may be beneficial. ”

“A majority of insomnia patients, especially the elderly and those with comorbid conditions, have difficulty staying asleep throughout the night,” said Thomas Roth, Ph.D., Director of Research, Chief of Sleep Medicine for the Henry Ford Hospital Sleep Disorders and Research Center . “These data show that ITI-007 can maintain sleep without impairing next day functioning.”

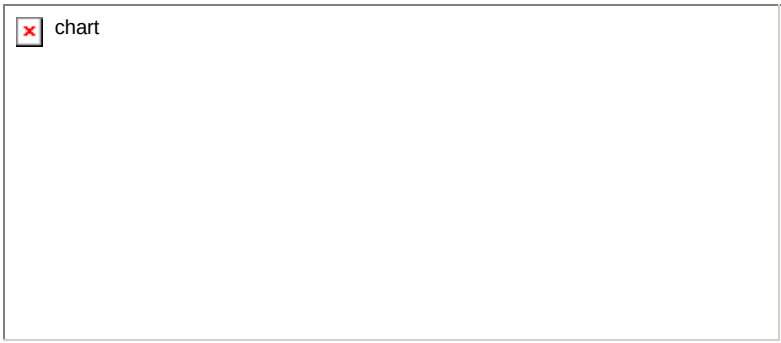
SUMMARY OF PHASE II SMI RESULTS

ITI-007 is an orally available investigational new drug being developed at low doses for the treatment of insomnia characterized by difficulty staying asleep, also referred to as sleep maintenance insomnia, and for insomnia associated with psychiatric disorders such as depression and post-traumatic stress disorder, and insomnia associated with neurologic disorders such as traumatic brain injury, Parkinson's disease, Alzheimer's disease and mild cognitive impairment. Previously announced interim results showed that patients with SMI treated with ITI-007 experienced dose-dependent increases in slow wave sleep (SWS) and dramatic decreases in wake after sleep onset (WASO) as determined by PSG. The final analysis (N=19) confirmed these results, meeting the primary and key secondary endpoints of the trial, and extended the findings to demonstrate remarkable efficacy in this patient population.

This Phase II trial was a double-blind, placebo controlled, 4-way crossover design comparing placebo to 3 doses of ITI-007 (1 mg, 5 mg and 10 mg) in patients with SMI. Analysis of key objectives in this study indicated that ITI-007 dose-dependently and significantly increased SWS ($p=0.002$) and decreased WASO ($p=0.001$). Consistent with the significant decrease in WASO, ITI-007 showed a statistical trend to decrease the number of awakenings ($p=0.071$). These large decreases in WASO also were reflected in the PSG recordings by increased total sleep time ($p<0.001$), decreased total time awake ($p<0.001$) and improved sleep efficiency (calculated by the proportion of the time spent sleeping while in bed, $p<0.001$).

Intra-Cellular Therapies believes that ITI-007 promotes natural, restorative sleep. In particular, ITI-007 did not cause rebound insomnia during early morning hours and did not suppress rapid eye movement (REM) sleep as some hypnotic agents do. ITI-007 significantly and dose-dependently increased the percent of SWS early in the night ($p=0.022$ for the first quarter of the night, $p=0.029$ for the second quarter of the night). Late in the night, towards morning, ITI-007 increased the percent of Stage 2 sleep ($p=0.048$ for the third quarter of the night, $p=0.004$ for the fourth quarter of the night). ITI-007 did not affect total duration of REM sleep ($p=0.124$) and ITI-007 did not affect latency to the first episode of REM ($p=0.143$). As predicted by its mechanism, ITI-007 did not affect latency to persistent sleep ($p=0.455$). Overall, the increases in SWS and Stage 2 sleep came at the expense of decreased percent time spent awake or drowsy (Stage 1 sleep, $p<0.001$). This was especially reflected by the ability of ITI-007 to decrease percent time spent awake or drowsy in the fourth quarter of the night compared to placebo ($p=0.002$), a time when other hypnotics tend to cause rebound increases in early morning wakefulness.

PHASE II RESULTS FOR ITI-007



The effects of ITI-007 on SWS are likely due to the ability of ITI-007 to potently antagonize 5HT2A receptors at low doses. The expanded pharmacological effects that emerge at higher doses contributed to the robust decreases in WASO at the 10 mg dose of ITI-007. The magnitude of this effect on WASO is larger than that seen with selective 5HT2A receptor antagonists and may be attributed to additional beneficial pharmacology that emerges at the higher doses tested. The highest dose tested (10 mg) is thought to fully occupy 5HT2A receptors while adding incremental amounts of dopamine receptor and serotonin reuptake transporter (SERT) occupancy. Together, these data suggest that ITI-007 induces a novel pattern of sleep improvement.

Doses of ITI-007 were safe and well-tolerated in patients with insomnia. The majority of the subjects experienced no adverse events (58%) or adverse events that were considered unrelated or unlikely related to study treatment (26%). Only 3 of the 19 subjects (16%) experienced an adverse event considered possibly related to study treatment; these were mild to moderate, were not dose-related and all resolved. No serious adverse events were reported. Importantly, ITI-007 did not impair next day cognition as measured by a battery of cognitive testing in the morning upon waking. ITI-007 caused no significant impairment of attention, vigilance, information processing or declarative memory as measured by the Leeds Psychomotor Battery, Digit Symbol Substitution Test or Word Pair Associates Test. Pharmacokinetic analyses revealed dose-related increases in exposure to ITI-007 and two metabolites with increasing dose.

These robust improvements in sleep suggest that ITI-007 will have utility in treating not only sleep maintenance insomnia 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).

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 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.

The present data show that ITI-007 is sleep promoting without having sedative properties and should not exhibit adverse 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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