December 9, 2013

Intra-Cellular Therapies Announces Positive Topline Phase II Clinical Results of ITI-007 for the Treatment of Schizophrenia

- Company to Host Conference Call on Monday, December 9, at 10:00 am Eastern Time to Discuss Trial Results -

New York, NY, December 9, 2013 - Intra-Cellular Therapies, Inc. ("we," "ITI" or "the Company"), a biopharmaceutical company focused on the development of therapeutics for central nervous system (CNS) disorders, announced today positive topline results from the Company's randomized, placebo- and active-controlled Phase II clinical trial of its lead drug candidate, ITI-007, in patients with acutely exacerbated schizophrenia. In this study, ITI-007 met the trial's pre-specified primary endpoint, improving symptoms associated with schizophrenia as measured by a statistically significant and clinically meaningful decrease in the Positive and Negative Syndrome Scale (PANSS) total score. The trial also met key secondary outcome measures related to efficacy on PANSS subscales and safety.

Many patients with schizophrenia have deficits in social function. Social function is the ability to recognize, understand, process and use external cues to solve problems, maintain work performance and conduct interpersonal relationships. Deficits in social function often remain after positive symptoms, such as hallucinations and delusions, have resolved in these patients. In the Phase II trial, ITI-007 exhibited a differentiating response profile across a broad range of symptoms that we believe is consistent with improvements in these social functioning deficits. The study also showed that ITI-007 was well-tolerated at the tested doses. ITI-007 demonstrated a favorable safety profile in the study without characteristic antipsychotic drug side effects or any serious adverse events.

"ITI-007 represents a new type of antipsychotic, where multiple behavioral actions are present and are dissociable by drug dose," said Carol A. Tamminga, MD, Chairman of the Psychiatry Department and Chief of Translational Neuroscience Research in Schizophrenia at the University of Texas Southwestern School of Medicine, and Chairman of ITI's Medical Advisory Board. "The robust antipsychotic efficacy of ITI-007 against a wide range of symptoms, augmented by its clean side effect profile demonstrated in this trial, suggests that ITI-007 may have broad utility in treating the multiple symptoms associated with schizophrenia in its acute and chronic phases with a single, stand-alone drug therapy."

"We are extremely pleased with the positive outcome of this clinical trial," stated Sharon Mates, PhD, President and Chief Executive Officer of ITI. "Not only was the primary objective of demonstrating antipsychotic efficacy achieved, but the study also revealed differentiating features of ITI-007, including improvements in a class of symptoms which may signal improved social function. We believe that this broad activity may indeed be related to ITI-007's mechanism of action, interacting broadly with the serotonin, dopamine and glutamate systems."

Dr. Mates continued, "Based on these findings we believe ITI-007 may be useful for treating both acute and residual phase schizophrenia with minimal side effects. We thank the patient volunteers who participated in our trial. We plan to continue the development of ITI-007, with a goal of rapidly bringing this innovative treatment to patients suffering from schizophrenia."

Topline data from this clinical trial are scheduled to be presented in a poster session on Tuesday, December 10, 2013 at the American College of Neuropsychopharmacology (ACNP) annual meeting in Hollywood, Florida.

ABOUT THE ITI-007-005 PHASE II CLINICAL TRIAL

The Phase II clinical trial, ITI-007-005, was a randomized, double-blind, placebo- and active-controlled clinical trial in patients with an acutely exacerbated episode of schizophrenia. In this trial, 335 patients were randomized to receive one of four treatments: 60 mg ITI-007, 120 mg ITI-007, 4 mg risperidone (active control) or placebo in a 1:1:1:1 ratio. Patients received study treatment orally once daily in the morning for 28 days. Of those randomized, 311 patients were included in the intent-to-treat primary analysis.

The primary endpoint for this clinical trial was change from baseline to Day 28 on the PANSS total score. The PANSS is a well-validated 30-item rating scale that measures the ability of a drug to reduce schizophrenia symptom severity (Kay et al., 1987, Schizophrenia Bulletin 13:261-276). The PANSS measures positive symptoms, such as delusions, suspiciousness, and hallucinations; negative symptoms, such as blunted affect, social and emotional withdrawal, and stereotyped thinking; and general psychopathology, such as anxiety, tension, depression, and active social avoidance. Safety and tolerability were also assessed.

ITI-007 at a dose of 60 mg demonstrated a statistically significant improvement in psychosis ($p = 0.017$) on the trial's pre-specified primary endpoint, which was change from baseline on the PANSS total score, compared to placebo. The primary statistical analysis was pre-specified and used a Mixed-Effect Model Repeated Measure method for handling missing data in the intent-to-treat (ITT) study population and a Bonferroni procedure to correct for multiple two-sided comparisons (each dose of ITI-007 compared to placebo). The trial's pre-specified sensitivity analysis on the primary endpoint used the analysis of covariance (ANCOVA) model and last observation carried forward (LOCF) method for handling missing data for the ITT population and confirmed the positive outcome with statistically significant improvements compared to placebo in patients receiving the 60 mg dose of ITI-007 ($p = 0.011$). ITI-007 at a dose of 60 mg also significantly improved the positive symptom subscale ($p < 0.05$) and the general psychopathology subscale ($p < 0.05$) on the PANSS after 28 days of treatment using the ANCOVA-LOCF on the ITT population.

The improvement in the total PANSS score in the 120 mg dose group did not reach statistical significance. We believe that it is possible that sedation, the most frequent side effect in the 120 mg dose group, interfered with the ability to detect an efficacy signal at this dose administered once daily in the morning. Approximately 32.5% of subjects randomized to 120 mg ITI-007 experienced sedation/somnolence, compared to 21% of subjects randomized to risperidone, 17% of subjects randomized to 60 mg ITI-007, and 13% randomized to placebo. We believe that nighttime administration may be more appropriate for testing the effectiveness of the 120 mg dose of ITI-007 in this patient population. In the trial, the 60 mg dose of ITI-007 was effective when administered once daily in the morning.

Consistent with preliminary indications from the interim analysis and with the drug's pharmacological profile, ITI-007 at a dose of 60 mg significantly improved certain items on the negative symptom and general psychopathology subscales consistent with improved social function. The study was statistically powered only on the primary endpoint. ITI-007 did significantly improve many secondary endpoints, although the study was not designed for significance on secondary endpoints and was not powered to detect statistical differences in subgroup analyses. Additional secondary endpoints, including depression, continue to be analyzed, and we expect that data will be presented at upcoming scientific conferences.

A high percentage (74%) of randomized subjects completed trial participation. Only 19% of subjects discontinued from study treatment during the 28-day study treatment period, and an additional 7% of subjects completed study treatment but were lost to follow up.

In the Phase 2 trial, ITI-007 was well-tolerated. The most frequent adverse event was sedation, as described above. There were no serious adverse events related to ITI-007. There were no clinically meaningful changes in safety measures with ITI-007. Notably, ITI-007 demonstrated a favorable metabolic profile with no increase of blood levels of glucose, insulin, cholesterol or triglycerides over a four-week treatment period. Moreover, in contrast to risperidone, 60 mg of ITI-007 was effective with no difference from placebo on weight change parameters, prolactin levels, extrapyramidal symptoms (EPS) or akathisia. ITI-007 was not associated with EPS as measured by the Simpson-Angus Scale, Barnes Akathisia Rating Scale, or Abnormal Involuntary Movement Scale. There was no increase in suicidal ideation or behavior with ITI-007.

The Company plans to request a meeting with the U.S. Food and Drug Administration (FDA) to discuss the Company's clinical development plan for ITI-007, including its plan to conduct separate, but overlapping, well-controlled clinical efficacy trials in schizophrenia and bipolar disorder. Additional clinical trials are planned to address the therapeutic utility of ITI-007 for the treatment of behavioral disturbances in dementia and Alzheimer's disease.

CONFERENCE CALL AND WEBCAST

The Company will host a conference call and webcast today, December 9, 2013 at 10:00 a.m. Eastern Time to discuss these results and to answer questions.

The live webcast and a replay may be accessed by visiting ITI's website at www.intracellulartherapies.com. Please connect to the Company's website at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call (877) 375-1350 (U.S.) or (315) 625-3229 (international) to listen to the live conference call. The conference ID number for the live call is 21627932. Please dial in approximately 10 minutes prior to the call. Telephone replay will be available approximately two hours after the call. To access the replay, please call (855) 859-2056 (U.S.) or (404) 537-3406 (international). The conference ID number for the replay is 21627932. The telephone replay will be available until December 16, 2013.

ABOUT ITI-007

ITI-007 is our lead drug development candidate, whose mechanisms of action, we believe, have the potential to yield a first-in-class antipsychotic therapy. In our pre-clinical and clinical trials to date, ITI-007 combines potent serotonin 5-HT2A receptor antagonism, dopamine receptor phosphoprotein modulation (DPPM), glutamatergic modulation and serotonin reuptake inhibition into a single drug candidate for the treatment of acute and residual schizophrenia. At dopamine D2 receptors, ITI-007 has been demonstrated to have dual properties and to act as both a post-synaptic antagonist and a pre-synaptic partial agonist. ITI-007 has also been demonstrated to stimulate phosphorylation of glutamatergic NMDA NR2B, or GluN2B, receptors

in a mesolimbic specific manner. We believe that this regional selectivity in brain areas thought to mediate the efficacy of antipsychotic drugs, together with serotonergic, glutamatergic, and dopaminergic interactions, may result in antipsychotic efficacy for positive, negative, affective and cognitive symptoms associated with schizophrenia. The serotonin reuptake inhibition could allow for antidepressant activity for the treatment of schizoaffective disorder, co-morbid depression, and/or as a stand-alone treatment for major depressive disorder. We believe ITI-007 may also be useful for the treatment of bipolar disorder and other psychiatric and neurodegenerative disorders, particularly behavioral disturbances associated with dementia, autism and other CNS diseases.

ABOUT SCHIZOPHRENIA

Schizophrenia is a disabling and chronic mental illness affecting over 1% of the world's population. Schizophrenia is characterized by multiple symptoms during an acute phase of the disorder that can include so-called "positive" symptoms, such as hearing voices, grandiose beliefs and suspiciousness or paranoia. These symptoms can be accompanied by additional, harder-to-treat symptoms, such as social withdrawal, blunted emotional response and speech deficits, collectively referred to as "negative" symptoms, difficulty concentrating and disorganized thoughts, or cognitive impairment, depression and insomnia. Such residual symptoms often persist even after the acute positive symptoms subside, and contribute substantially to the social and employment disability associated with schizophrenia. Current antipsychotic medications provide some relief for the symptoms associated with the acute phase of the disorder, but they do not effectively treat the residual phase symptoms associated with chronic schizophrenia. Currently available medications used to treat acute schizophrenia are limited in their use due to side effects that can include movement disorders, weight gain, metabolic disturbances, and cardiovascular disorders. There is an unmet medical need for new therapies that have improved side effect and efficacy profiles.

ABOUT INTRA-CELLULAR THERAPIES

Intra-Cellular Therapies (ITI) is developing novel drugs for the treatment of neuropsychiatric and neurodegenerative disease and other disorders of the CNS. The Company is developing ITI-007 for the treatment of schizophrenia and other neuropsychiatric and neurological disorders. This Phase II trial follows a favorable Phase I/II study demonstrating the safety and tolerability of ITI-007 across a broad range of doses in patients with stable schizophrenia. In the Phase I/II trial, exploratory clinical measures revealed signals consistent with antipsychotic efficacy for positive and negative symptoms and antidepressant efficacy for ITI-007.

The Company is also developing other drug candidates. In February 2011, ITI entered into a collaboration with the Takeda Pharmaceutical Company to develop certain phosphodiesterase 1 (PDE1) inhibitors for the treatment of cognitive deficits in schizophrenia and other CNS disorders. In February 2013, ITI announced the successful completion of a Phase I single rising dose study of the lead molecule in the ITI/Takeda collaboration, ITI-214. ITI has additional programs in the areas of Parkinson's disease, Alzheimer's disease, depression, and cardiovascular disease.

FORWARD-LOOKING STATEMENTS

This news release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, the results of our Phase 2 clinical trial of ITI-007 in patients with acutely exacerbated schizophrenia, the potential for ITI-007 to represent a new type of antipsychotic and to have broad utility in treating multiple symptoms associated with schizophrenia in its acute and chronic phases with a single, stand-alone therapy, the ability of ITI-007 to improve a class of symptoms that may signal improved social function and the potential relationship with the drug candidate's mechanism of action, the potential use of ITI-007 for the treatment of both acute and residual phase schizophrenia with minimal side effects, our plans to present topline data from the Phase 2 clinical trial at upcoming scientific conferences, our plans to request a meeting with the FDA to discuss our clinical development plan for ITI-007, our plans to develop ITI-007 for the treatment of behavioral disturbances in dementia and in other indications, our beliefs concerning the results in the 120 mg dose group and potential changes in administration, our beliefs concerning the properties of ITI-007 and its potential therapeutic uses under the caption "About ITI-007," our statements about an unmet medical need for new therapies to treat schizophrenia, and our research and development efforts and plans under the caption "About Intra-Cellular Therapies." All such forward-looking statements are based on management's present expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such statements. These risks and uncertainties include, but are not limited to the following: our current and planned clinical trials for ITI-007 and our other product candidates may not be successful or may take longer and be more costly than anticipated; product candidates that appeared promising in early research and clinical trials may not demonstrate safety and/or efficacy in larger-scale or later clinical trials; our reliance on collaborative partners and other third-parties for further clinical trials, development and commercialization of our product candidates; the costs associated with our research, development and other activities may exceed those that we estimate; the conduct and results of preclinical and clinical studies of our product candidates may pose challenges for the ongoing development of our product candidates; we may experience difficulties or delays in obtaining regulatory approvals to market products; we may experience difficulties in raising additional capital to pursue our operating plans, which could materially adversely affect our ability to continue as an enterprise; our

intellectual property may not provide the protection we require, and we may be subject to third-party intellectual property claims; we may fail to comply with extensive regulatory requirements; we may experience safety issues with ITI-007 or other product candidates that render such potential products of limited value; as well as risks related to key employees, markets, economic conditions, health care reform, prices and reimbursement rates and the other risk factors discussed under the heading "Risk Factors" contained in our Current Report on Form 8-K filed with the Securities and Exchange Commission on October 31, 2013, as well as any updates to those risk factors filed from time to time in our periodic and current reports filed with the Securities and Exchange Commission. The information contained in this press release is believed to be current as of the date of original issue. We do not intend to update any of the forward-looking statements after the date of this release to conform these statements to actual results or to changes in our expectations, except as required by law.

CONTACT:

Allen A. Fienberg, Ph.D.
Vice President
Business Development of Intra-Cellular Therapies, Inc.
+1-212-923-3344

Burns McClellan, Inc.
Lisa Burns/Angeli Kolhatkar (Investors)
Justin Jackson (Media)
\n jjackson@burnsmc.com
Phone +1 (212) 213-0006