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Intra-Cellular Therapies Announces Positive Top-Line Results From the First Phase 3 Trial of ITI-007 in Patients With Schizophrenia and Confirms the Unique Pharmacology of ITI-007 in a Separate Positron Emission Tomography Study

- *ITI-007 60 mg once-daily met the primary and key secondary efficacy endpoints in the Phase 3 trial*
- *ITI-007 60 mg significantly improved social functioning as measured by the Personal and Social Performance Scale*
- *ITI-007 demonstrated a safety and tolerability profile that did not differ from placebo on key parameters of body weight, cardiovascular function and vital signs, glucose, lipids, prolactin, akathisia and other motoric disturbances*

Intra-Cellular Therapies to Host a Conference Call Today at 8:30 a.m. ET to Discuss Results

NEW YORK, Sept. 16, 2015 (GLOBE NEWSWIRE) -- Intra-Cellular Therapies, Inc. (NASDAQ:ITCI), a biopharmaceutical company focused on the development of therapeutics for central nervous system (CNS) disorders, today announced positive results from the first Phase 3 clinical trial of ITI-007 for the treatment of patients with schizophrenia. In this trial, once-daily ITI-007 60 mg met the primary endpoint and demonstrated antipsychotic efficacy with statistically significant superiority over placebo at Week 4 (study endpoint) as measured by the change from baseline on the Positive and Negative Syndrome Scale (PANSS) total score (p=0.022). Moreover, ITI-007 60 mg showed significant antipsychotic efficacy as early as week 1, which was maintained at every time point throughout the entire study. ITI-007 60 mg also met the key secondary endpoint of statistically significant improvement on the Clinical Global Impression Scale for Severity of Illness (CGI-S; p=0.003). These findings confirm the positive results demonstrated by ITI-007 60 mg in the Company's Phase 2 study. Consistent with previous studies, ITI-007 had a favorable safety and tolerability profile as evidenced by motoric, metabolic, and cardiovascular characteristics similar to placebo, and no clinically significant changes in akathisia, extrapyramidal symptoms, prolactin, body weight, glucose, insulin, or lipids.

The Company also announced top-line data from a separate clinical study using positron emission tomography (PET) in patients with schizophrenia. In this trial, ITI-007 60 mg was associated with a mean of approximately 40% striatal dopamine D_2 receptor occupancy. As predicted by preclinical and earlier clinical data, ITI-007 demonstrated antipsychotic effect at relatively low striatal D_2 receptor occupancy, lower than the occupancy range required by most other antipsychotic drugs. Unlike any existing schizophrenia treatment, this dopamine receptor phosphoprotein modulator, or DPPM, acts as a pre-synaptic partial agonist and post-synaptic antagonist at D_2 receptors. This mechanism likely contributes to the favorable safety profile of ITI-007, with reduced risk for hyperprolactinemia, akathisia, extrapyramidal symptoms, and other motoric side effects. The data from both clinical trials will be presented at upcoming scientific meetings.

"ITI-007 demonstrated efficacy in the treatment of patients with schizophrenia," said Dr. Carol Tamminga, Professor and Chairman, Department of Psychiatry, University of Texas Southwestern Medical School, and the Lou and Ellen McGinley Distinguished Chair in Psychiatric Research. "To have achieved efficacy at lower dopamine receptor occupancy levels more commonly associated with clozapine, arguably the most efficacious antipsychotic, while maintaining a placebo-like safety and tolerability profile is a remarkable advance in the development of drugs for schizophrenia."

"We are very encouraged by the positive results of our first Phase 3 trial. These data confirm the findings from our previous placebo- and risperidone active-controlled, randomized Phase 2 trial. The antipsychotic effect of 60 mg is confirmed and shows itself to be well-tolerated along with a safety profile similar to placebo," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "Patients deserve a treatment choice which gives them symptom relief without the associated movement disorders, metabolic disturbances or cardiovascular effects observed with many antipsychotics. We are excited about our progress towards delivering a novel treatment option for patients."

About the Phase 3 ITI-007-301 Trial

This randomized, double-blind, fixed-dose, placebo-controlled Phase 3 clinical trial was conducted at 12 sites in the United States with 450 patients randomized (1:1:1) to receive either ITI-007 60 mg or 40 mg or placebo once daily in the morning for four weeks. Patients were diagnosed with schizophrenia (using DSM-5 criteria) and were required to have an acute exacerbation of psychotic symptoms. The pre-specified primary efficacy measure was change from baseline versus placebo at study endpoint (4 weeks) on the centrally rated PANSS total score. The key secondary endpoint was the centrally rated CGI-S. Trial participants had a mean PANSS score of 89.8 at baseline indicative of being markedly ill. Once daily morning dosing allowed for comprehensive safety assessments during the day throughout the study, including measurement of cardiovascular function, vital signs, body weight, and laboratory assessments. This is the first of two Phase 3 clinical trials intended to evaluate

the efficacy, safety and tolerability of ITI-007 for the treatment of schizophrenia.

Primary and Key Secondary Efficacy Endpoints

ITI-007 60 mg met the primary efficacy endpoint by demonstrating a statistically significant improvement versus placebo on the PANSS total score, in the intent-to-treat (ITT) study population (least squares [LS] mean change from baseline -14.5 points, effect size [ES]=0.30, p=0.022 versus -10.3 points change from baseline for placebo). ITI-007 showed a dose-related improvement in symptoms of schizophrenia with the 40 mg dose approximating the trajectory of improvement seen with the 60 mg dose, but the effect with 40 mg did not reach statistical significance on the primary endpoint (-12.9 points, ES=0.18, p=0.164). The pre-specified primary statistical analysis used a Mixed-Effect Model Repeated Measure (MMRM) method for handling missing data in the ITT study population and was corrected for multiple comparisons.

ITI-007 60 mg met the key secondary endpoint demonstrating a statistically significant improvement versus placebo on the CGI-S, a well-established and clinically useful rating tool to determine a global level of illness severity (ES=0.39, p=0.003). ITI-007 40 mg also demonstrated a statistically significant improvement versus placebo on the CGI-S (ES=0.30, p=0.025), though not formally tested against placebo since it did not separate on the primary endpoint.

Safety & Tolerability

Dosing in the morning, as in our earlier Phase 2 study, allowed for a comprehensive safety assessment throughout the study. ITI-007 was well-tolerated and demonstrated a safety profile that did not differ from placebo. The majority of adverse events were mild in nature and the rates of discontinuation due to adverse events for either dose of ITI-007 were low and similar to placebo. Of particular clinical importance in schizophrenia, both doses of ITI-007 showed no significant difference from placebo on weight gain (mean change from baseline body weight over 4 weeks of treatment). Furthermore, no significant differences were observed compared to placebo on metabolic parameters (including cholesterol, triglycerides, glucose and insulin) or on prolactin levels. Key measures of cardiovascular function (including heart rate, QTc intervals and other ECG parameters) were similar between ITI-007 and placebo. These findings are consistent with previous studies and provide further evidence that ITI-007 is not associated with the usual side effects of existing medications for schizophrenia.

The most commonly reported adverse events that were considered at least possibly related to ITI-007 and that were observed at rates greater than 5% and at least twice the rate of placebo were limited to somnolence (predominantly mild with a frequency of 10.7% for 40 mg and 17.3% for 60 mg versus 4.0% for placebo), mild sedation (9.3% for 40 mg and 12.0% for 60 mg versus 5.4% for placebo), and fatigue (predominantly mild with a frequency of 4.0% for 40 mg and 5.3% for 60 mg versus 1.3% for placebo). Adverse events observed in the trial were generally mild with low, placebo-like discontinuation rates for ITI-007. Akathisia and other movement disturbances, did not differ significantly from placebo, as measured by adverse event reporting, the Simpson-Angus Scale, the Barnes Akathisia Rating Scale, or the Abnormal Involuntary Movement Scale. Importantly, there was no increase in suicidal ideation or suicidal behavior with ITI-007 over placebo.

Additional Efficacy Data

ITI-007 60 mg demonstrated early control over symptoms associated with schizophrenia as demonstrated by statistically significant improvement after only 1 week of treatment compared to placebo as measured by the PANSS total score and as measured by the PANSS Positive Symptom Subscale. The effect of ITI-007 60 mg was maintained with statistically significant separation from placebo at each weekly measurement of the PANSS total score and the PANSS Positive Symptom Subscale for the full duration of the study treatment period. ITI-007 40 mg demonstrated numerically better PANSS total and PANSS Positive Symptom Subscale scores compared to placebo at every visit, but the improvement with 40 mg did not reach statistical significance at study endpoint. Furthermore, both doses of ITI-007 improved the PANSS Negative Symptom Subscale score more than placebo in the ITT population, but the improvement did not reach statistical significance in this 4 week study. These and additional data will be presented at upcoming scientific meetings.

ITI-007 60 mg demonstrated improved social functioning as measured by the Personal and Social Performance Scale (PSP) with a statistically significant improvement compared to placebo. The PSP scale is a validated scale that measures a person's level of psychosocial functioning across four important social domains: socially useful activities, personal and social relationships, self-care, and disturbing and aggressive behavior. ITI-007 40 mg showed a numerical improvement in PSP compared to placebo, but did not reach statistical significance.

About the ITI-007-008 Positron Emission Tomography (PET) Study

This open-label study was conducted in patients diagnosed with schizophrenia who were otherwise healthy and stable with respect to their psychosis. After washout from their previous antipsychotic medication for at least two weeks, PET was used to determine target occupancy in brain regions at baseline (drug-free) and again after two weeks of once daily ITI-007 oral administration. [^{11}C]-Raclopride was used as the radiopharmaceutical for imaging striatal dopamine D_2 receptors in patients receiving 60 mg ITI-007 (N=10). Other radiopharmaceuticals for imaging other targets and other doses of ITI-007 were included

as exploratory endpoints; exploratory data will be reported separately.

The study demonstrated mean peak striatal D_2 receptor occupancy of approximately 40% with a range of peak occupancy up to 51%. These data extend previous findings of dose-related striatal D_2 receptor occupancy after a single dose across a lower dose range of ITI-007 measured in healthy volunteers: mean of 12% (up to 17%) at 10 mg, 19% (up to 20%) at 20 mg, 27% (up to 32%) at 30 mg, and 29% (up to 39%) at 40 mg (as published in Davis et al., Psychopharmacology 232:2863-2872, 2015).

Conference Call and Webcast Details

Intra-Cellular Therapies will host a live conference call and webcast today at 8:30 a.m. ET, during which management will discuss the top-line results of our Phase 3 trial and PET study. The live webcast and subsequent replay may be accessed by visiting the Company's website at www.intracellulartherapies.com. Please connect to the Company's website at least 5-10 minutes prior to the live webcast to ensure adequate time for any necessary software download. Alternatively, please call 1-844-835-6563 (U.S.) or 1-970-315-3916 (international) to listen to the live conference call. The conference ID number for the live call is 42973722. Please dial in approximately 10 minutes prior to the call.

About ITI-007

ITI-007 is our lead drug development candidate with mechanisms of action that, 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-HT_{2A} 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 D_2 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 $GluN_{2B}$ 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, disorganized thinking, grandiose beliefs and suspiciousness or paranoia. These symptoms can be accompanied by additional, harder-to-treat symptoms, such as social withdrawal and blunted emotional response and expression, collectively referred to as "negative" symptoms, difficulty concentrating 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 and psychosocial impairment 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 Inc.

Intra-Cellular Therapies is developing novel drugs for the treatment of neuropsychiatric and neurodegenerative diseases and diseases of the elderly, including Parkinson's and Alzheimer's disease. The Company is developing its lead drug candidate, ITI-007, for the treatment of schizophrenia, bipolar disorder, behavioral disturbances in dementia, depression, and other neuropsychiatric and neurological disorders. ITI-007, a first-in-class molecule, is in Phase 3 clinical development for the treatment of schizophrenia. The Company is also utilizing its phosphodiesterase platform and other proprietary chemistry platforms to develop drugs for the treatment of CNS and other disorders.

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, our clinical and nonclinical development plans; the progress, timing and results of

our clinical trials; the safety and efficacy of our product development candidates; our beliefs about the potential uses and benefits of ITI-007; our plans to present or report additional data; 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, other studies 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 earlier 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 development of our product candidates; and the other risk factors discussed under the heading "Risk Factors" contained in our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the Securities and Exchange Commission (SEC), as well as any updates to those risk factors filed from time to time in our periodic and current reports filed with the SEC. All statements contained in this press release are made only as of the date of this press release, and we do not intend to update this information unless required by law.

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