December 9, 2015

Intra-Cellular Therapies Presents Additional Efficacy and Safety Data From the Positive Phase 3 Clinical Trial of ITI-007 for the Treatment of Schizophrenia and From the Positron Emission Tomography Study

Intra-Cellular Therapies to Host a Conference Call Thursday, December 10, 2015 at 8:30 am EST to Discuss the Data

NEW YORK, Dec. 9, 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 additional data from the first Phase 3 clinical trial of ITI-007 for the treatment of patients with schizophrenia (ITI-007-301) and the ITI-007 Positron Emission Tomography (PET) study in patients with schizophrenia at the 54th annual meeting of the American College of Neuropsychopharmacology (ACNP)Â in Hollywood, Florida.

Poster W166 entitled "Clinical Development of ITI-007 for the Treatment of Schizophrenia" described additional data from the ITI-007-301 trial, topline results of which were announced in September 2015:

ITI-007 60 mg improved symptoms of schizophrenia and met the primary endpoint demonstrating statistically significant superiority over placebo at Day 28 as measured by the Positive and Negative Syndrome Scale (PANSS) total score. The 40 mg dose approximated the trajectory of improvement seen with the 60 mg dose, but the effect with 40 mg did not reach statistical significance on the PANSS total score.

Both the 60 mg and 40 mg doses of ITI-007 significantly reduced the PANSS positive symptom subscale score versus placebo at study endpoint and at earlier time points.Â

ITI-007 60 mg met the key secondary endpoint demonstrating statistically significant improvement on the Clinical Global Impression scale for Severity of Illness (CGI-S). ITI-007 40 mg also demonstrated a statistically significant improvement versus placebo on the CGI-S. The CGI-S is a well-established and clinically useful rating tool which provides a clinician's view of the patient's global level of illness severity.

Moreover, ITI-007 significantly improved social function as evidenced by improvements in the PANSS-derived Prosocial Factor and the Personal and Social Performance Scale.Â ITI-007 qualitatively improved the PANSS negative symptoms subscale score in this acute patient population.

ITI-007 was well-tolerated and demonstrated a safety profile that did not differ from placebo. This study had a high percentage of patients completing treatment, with time to treatment discontinuation (due to any reason) being statistically significantly better with 60 mg ITI-007 than with placebo. The only treatment-emergent adverse events considered at least possibly related to ITI-007, administered orally once daily in the morning, occurring in greater than 5% of patients and at least twice the rate of placebo were somnolence, sedation, and fatigue, all predominantly mild.

ITI-007's motoric, metabolic, and cardiovascular profile was similar to placebo, and there were no clinically significant changes in akathisia, extrapyramidal symptoms, prolactin, body weight, glucose, insulin, and lipids.

Second generation antipsychotic drugs (SGAs) for schizophrenia expose patients to increased risk of diabetes and other associated diseases including cardiovascular disease, resulting in a significant burden on our healthcare system. SGAs also have motoric adverse events impacting patient quality of life, often leading to poor medication adherence. The Company believes existing data suggest that ITI-007 does not impact these metabolic, cardiovascular and motoric parameters in patients with schizophrenia.

"The Phase 3 trial demonstrated that ITI-007 isÂ efficacious in the treatment of patients with schizophrenia while possessing a favorable safety and tolerability profile particularly in relation to metabolic, motoric and cardiovascular parameters," said Dr. Sharon Mates, Chairman and CEO ofÂ Intra-Cellular Therapies. "These data are consistent with prior results seen in our Phase 2 study and add further evidence to our belief that ITI-007 may represent an improvement on existing therapies for patients with schizophrenia."

Poster W174 entitled "Further Characterizing Brain Receptor Occupancy with ITI-007:Â Results from a Positron Emission

Tomography (PET) Study in Patients" highlighted data from the ITI-007 PET study in patients with schizophrenia:

ITI-007 was safe and well tolerated in this study. In this study, mean striatal D2 receptor occupancy at an effective antipsychotic dose of 60 mg ITI-007 was about 40%. This PET study in patients with stable schizophrenia further adds to the information gleaned regarding brain receptor occupancy levels from a prior PET study in healthy volunteers. ITI-007 demonstrates relatively low striatal D2 receptor occupancy at an antipsychotic efficacious dose, and has a decreased risk for induction of D2 mediated side effects, including extrapyramidal side effects, akathisia, and hyperprolactinemia.Â Together, these data suggest that ITI-007 may represent an exciting new first-in-class treatment for schizophrenia.

Conference Call and Webcast Details

The Company will host a live conference call and webcast December 10, 2015 atÂ 8:30 AM Eastern Standard TimeÂ to discuss the additional data presented at ACNP. The live webcast and subsequent replay may be accessed by visiting the Company's website atÂ 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 2009462. Please dial in approximately 10 minutes prior to the call. The webcast will be available on the Company's website until December 14, 2015.

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}Â 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_2Â 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 $GluN_{2B}$Â 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

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 non-clinical 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; 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 endedÂ December 31, 2014Â filed with theÂ Securities and Exchange CommissionÂ (SEC), as well as any updates to those risk factors filed from time to time in our periodic and current reports filed with theÂ 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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