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Intra-Cellular Therapies Presents Additional ITI-007 Data at the 5th Biennial Schizophrenia International Research Society (SIRS) Conference

NEW YORK, April 06, 2016 (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 it delivered an oral presentation and presented several posters featuring data on ITI-007, the Company's lead drug candidate at the 5th Biennial Schizophrenia International Research Society (SIRS) Conference being held in Florence, Italy.

The oral presentation and two poster presentations featured additional efficacy and safety data from ITI-007-301, the Company's recently completed Phase 3 clinical trial in patients with schizophrenia. An additional poster presentation featured data from the ITI-007 Positron Emission Tomography (PET) study in patients with schizophrenia. Top-line data from both trials were announced in September 2015 and subsequently presented at the 54th annual meeting of the American College of Neuropsychopharmacology (ACNP) in December 2015.

Poster #S66 entitled "ITI-007 Exhibits Unique Pharmacology: Combined Results from Positron Emission Tomography (PET) Studies in Healthy Volunteers and Patients with Schizophrenia," was presented on Sunday, April 3rd. This PET study highlights ITI-007's unique pharmacological profile via serotonergic, dopaminergic, and glutamatergic pathways. ITI-007 was safe and well-tolerated and demonstrated dose-related occupancy of human brain dopamine D_2 receptors, 5-HT_{2A} receptors, and serotonin transporters. At a dose of 60 mg, ITI-007 demonstrated relatively low, about 40% mean peak striatal D_2 receptor occupancy in patients with schizophrenia at plasma steady state. Taken into context with data from other clinical trials, ITI-007 60 mg was effective in reducing psychosis in patients with schizophrenia at relatively low striatal D_2 receptor occupancy, lower than the occupancy range required by most other antipsychotic drugs. This mechanism, along with ITI-007's potent interactions at 5-HT_{2A} receptors, serotonin transporters and D_1 receptors, likely contributes to the efficacy of ITI-007 with improved psychosocial function and favorable motoric tolerability representing a potentially novel approach to the treatment of schizophrenia and other neuropsychiatric disorders. Additional data regarding receptor occupancy within specific brain regions such as the ventral striatum were presented.

Poster #M67 entitled "Positive Phase 3 Clinical Trial of ITI-007 for the Treatment of Schizophrenia: Secondary Endpoints and Subgroup Analyses from a Randomized, Double-Blind, Placebo-Controlled Trial," was presented on Monday, April 4th. In this trial, once-daily ITI-007 60 mg met the primary endpoint and demonstrated efficacy with statistically significant superiority over placebo at Day 28 as measured by the Positive and Negative Syndrome Scale (PANSS) total score (p=0.022). Moreover, ITI-007 60 mg showed significant efficacy as early as week 1 on both the PANSS total score and PANSS Positive Symptom subscale score, 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 of Severity of Illness (CGI-S) (p=0.003). Both doses (ITI-007 40 mg and 60 mg) improved global severity of illness, positive symptoms and prosocial behavior.

A high treatment completion rate was observed with ITI-007 (87% of patients completed treatment on ITI-007 60 mg, 82% completed on ITI-007 40 mg, and 75% completed on placebo). Patients randomized to ITI-007 60 mg demonstrated a statistically significant longer time to treatment discontinuation due to any reason compared to placebo (p=0.006) and a statistically significant longer time to treatment discontinuation due to lack of efficacy (p=0.01). Baseline characteristics of the studied patient population indicated a mean of 17 years since first diagnosis and markedly ill at baseline with a mean baseline PANSS total score of 89.8 and a mean baseline CGI-S score of 4.8.

Poster #T66 entitled "Positive Phase 3 Clinical Trial of ITI-007 for the Treatment of Schizophrenia: Safety Results from a Randomized, Double-Blind, Placebo-Controlled Trial," was presented on Tuesday, April 5th. ITI-007 given once daily in the morning was well-tolerated with no dose titration and demonstrated a safety profile that did not differ from placebo in patients with acutely exacerbated schizophrenia. The number of patients who discontinued treatment in this trial due to an adverse event was low and the time to treatment discontinuation due to an adverse event was not statistically significantly different from placebo for either dose of ITI-007. Patients randomized in this trial included 77.1% males with a mean age of 42.4 years. Administered orally once daily in the morning, the only treatment-emergent adverse event considered at least possibly related to ITI-007 occurring in ≥5% of patients and at least twice the rate of placebo were somnolence, sedation and fatigue, all predominantly mild. ITI-007 showed a motoric profile similar to placebo according to adverse event reports or when objectively measured by the Simpson Angus Scale, the Barnes Akathisia Rating Scale, and the Abnormal Involuntary Movement Scale. There was no clinically meaningful increase in prolactin, rather ITI-007 (60 mg) significantly decreased

prolactin (p=0.05), consistent with its mechanism of action as a dopamine D_2 receptor partial agonist. ITI-007 also showed a metabolic profile similar to placebo.

The oral presentation at SIRS entitled "Positive Phase 3 Clinical Trial of ITI-007 for the Treatment of Schizophrenia: Efficacy Results from a Randomized, Double-Blind, Placebo-Controlled Trial," was presented on Tuesday, April 5th and included an overview of the data presented in the posters.

"These data provide additional insights into the positive efficacy, safety and tolerability results seen in our ITI-007 studies in patients with schizophrenia, suggesting there is a broad beneficial effect with ITI-007 in schizophrenia and potentially across multiple indications," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "We believe, if approved, ITI-007 may provide an advancement in the treatment of schizophrenia by offering patients an effective therapy and the possibility of achieving long-term benefits by staying on treatment."

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 therapy for multiple therapeutic indications. 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, as well as for the treatment of bipolar disorder, including bipolar depression. 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 efficacy for a broad array of symptoms associated with schizophrenia and bipolar disorder with improved psychosocial function. The serotonin reuptake inhibition potentially allows for antidepressant activity in 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 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 and bipolar depression. 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 detailed in our public filings with the Securities and Exchange Commission. 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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