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Intra-Cellular Therapies Presents the ITI-007 Clinical Development Program in Schizophrenia at the CNS Summit 2016 Annual Conference

NEW YORK, Oct. 31, 2016 (GLOBE NEWSWIRE) -- Intra-Cellular Therapies, Inc. (NASDAQ:ITCI) today announced presentation (in oral and poster forms) of results from its clinical development program in schizophrenia that has replicated the efficacy of ITI-007 60 mg in two studies and found it to be safe and well tolerated in three large, well-controlled clinical trials: ITI-007-005, ITI-007-301 and ITI-007-302. Results from these trials were presented at the CNS Summit 2016 Annual Conference, held in Boca Raton, Florida October 27-30.

Across all three trials, ITI-007 60 mg improved symptoms of schizophrenia with a similar trajectory and magnitude of improvement from baseline to endpoint on the primary efficacy measure, the PANSS total score. These robust improvements in psychotic symptoms were statistically significant versus placebo in Studies ‘005 and ‘301 but not in Study ‘302 due in part to an unusually high placebo response. In all three of these studies, ITI-007 was well-tolerated and exhibited a safety profile similar to placebo. In addition, in the studies where risperidone was used as the active control (Studies ‘005 and ‘302), ITI-007 was statistically significantly better than risperidone on key safety and tolerability parameters. The Company believes that the two large, well-controlled positive studies (‘005 & ‘301) along with supportive findings from the third study (‘302) collectively provide evidence of the efficacy and safety of ITI-007 for the treatment of schizophrenia.

The Company's CNS summit poster presentation can be found on our website, available here. The Company will present additional analyses from the ITI-007 schizophrenia program at future scientific conferences.

"We are excited that our schizophrenia clinical development program to date has replicated the efficacy of ITI-007 60 mg in two large well-controlled studies and we are encouraged that these data and additional data from study '302, again describing a placebo-like safety profile with clinical advantages over risperidone, have been so well-received by the medical community at CNS Summit. We look forward to advancing this new treatment option for patients and to discussing the totality of these data with the FDA," said Dr. Sharon Mates, Chairman and CEO of ITCI.

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.

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-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, as well as for the treatment of bipolar disorder, including bipolar depression, and the treatment of agitation associated with dementia, including Alzheimer's disease. 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 have affinity for dopamine D1 receptors and indirectly stimulate phosphorylation of glutamatergic NMDA 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 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 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, bipolar depression and agitation associated with dementia, including Alzheimer's disease. 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 beliefs about the potential uses and benefits of ITI-007; 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 unmet medical needs; 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 proposals with respect to the regulatory path for our product candidates may not be acceptable to the FDA; 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.

Contact:
Juan Sanchez, M.D.
Vice President
Corporate Communications and Investor Relations of Intra-Cellular Therapies, Inc.
Phone: 212-923-3344

Burns McClellan, Inc.
Lisa Burns
Justin Jackson (Media)
Email: jjackson@burnsmc.com
Phone: 212-213-0006