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Intra-Cellular Therapies Reports Completion of Enrollment of ITI-007-302 Phase 3 Clinical Trial for the Treatment of Schizophrenia

NEW YORK, June 30, 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 completion of enrollment in the second Phase 3 clinical trial (ITI-007-302) of the Company's lead product candidate ITI-007 for the treatment of schizophrenia. The Company anticipates topline data will be available later this year.

"The completion of enrollment in our 302 Phase 3 trial is a major milestone in our mission to advance ITI-007 as a new treatment option for patients suffering from mental illness," said Sharon Mates Ph.D., Chairman and CEO of Intra-Cellular Therapies, Inc. "We believe ITI-007 has the potential to advance the treatment of schizophrenia by providing efficacy with a reduced side effect burden, thereby allowing patients to stay on treatment and benefit from enhanced social functioning."

About the ITI-007-302 Phase 3 Trial

The Phase 3 clinical trial, ITI-007-302, is a randomized, double-blind, placebo- and active-controlled clinical trial in patients with an acutely exacerbated episode of schizophrenia. In this trial, 696 patients were randomized to receive one of four treatments: ITI-007 60 mg, ITI-007 20 mg, risperidone 4 mg (active control) or placebo in a 1:1:1:1 ratio. Patients receive study treatment orally once daily in the morning for 6 weeks. Clinical conduct includes an approximate one-week screening period before randomization followed by the 6-week study treatment period. Prior to discharge from the study, patients are switched to a standard-of-care antipsychotic treatment during a five-day inpatient stabilization period. Patients are instructed to return for an outpatient safety follow-up visit approximately two weeks following the last dose of study treatment (study day 54). The study is being conducted in 13 clinical sites throughout the United States.

The primary endpoint for this clinical trial is change from baseline at Day 42 on the Positive and Negative Syndrome Scale (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. The key secondary endpoint is change from baseline at Day 42 on the Clinical Global Impression scale for Severity of Illness (CGI-S) that provides a clinician's expert assessment of the patient's overall symptom severity. Additional secondary endpoints and other measures, including safety and tolerability, which may highlight differentiating clinical features of ITI-007 are also being assessed. ITI-007 60 mg has demonstrated a statistically significant improvement versus placebo in schizophrenia symptoms and a favorable safety and tolerability profile in two prior late-stage clinical studies.

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-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 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 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 patients with dementia, including Alzheimer's disease, 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 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; 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 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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