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Intra-Cellular Therapies Presents New Data from the Phase 2 Clinical Trial of ITI-007 in Schizophrenia at the 167th Annual Meeting of the American Psychiatric Association

NEW YORK, May 6, 2014 /GLOBE NEWSWIRE/ -- Intra-Cellular Therapies, Inc. (NASDAQ: ITCI), a biopharmaceutical company focused on the development of therapeutics for central nervous system (CNS) disorders is presenting additional data from the Phase 2 clinical trial of ITI-007 in schizophrenia at the 167th Annual Meeting of the American Psychiatric Association (APA) being held in New York, NY.

A summary of the information contained in the presentations is set forth below.

Poster NR8-173: "ITI-007 for the Treatment of Schizophrenia: A Randomized, Double-Blind, Placebo- and Active-Controlled Phase 2 Trial" is being presented today by Kimberly E. Vanover, et al. The poster provides further analyses of the Phase 2 clinical trial of ITI-007, whose topline results and secondary analyses were previously presented in December 2013 and April 2014.

Primary endpoint

ITI-007 at a dose of 60 mg demonstrated a statistically significant improvement in psychosis on the trial's pre-specified primary endpoint, which was a change from baseline on the PANSS total score, compared to placebo on Study day 28 ($p = 0.017$; MMRM-ITT).

Safety and tolerability

The percentage of ITI-007 randomized patients withdrawing from the study due to adverse events was low and comparable to placebo (0-2%). In the study, ITI-007 was well tolerated and the most frequent adverse event was sedation and somnolence. Approximately 32.5% of subjects randomized to 120 mg of ITI-007 experienced sedation/somnolence, compared to 21% of subjects randomized to risperidone, 17% of subjects randomized to 60 mg ITI-007, and 13% randomized to placebo. ITI-007 was efficacious at a dose of 60 mg with no statistically significant increase in treatment-emergent adverse events compared to placebo.

The percentage of patients taking ITI-007 reporting akathisia was similar to placebo (1-2%). Seven percent (7%) of patients on risperidone reported akathisia. Patients taking ITI-007 had no evidence of extrapyramidal symptom (EPS) signals as measured by BARS (Barnes Akathisia Rating Scale), SAS (Simpson-Angus Scale), or AIMS (Abnormal Involuntary Movement Scale).

Metabolic and body weight side effect profile: ITI-007, at 60 mg and 120 mg, demonstrated a favorable metabolic profile with no clinically significant changes on blood insulin levels, glucose, total cholesterol and triglycerides versus baseline. Notably, when compared to risperidone, both doses of ITI-007 demonstrated statistically significant lower blood glucose levels, total cholesterol and triglycerides and 120 mg ITI-007 demonstrated statistically significant lower insulin levels versus risperidone.

60 mg and 120 mg of ITI-007 did not result in a meaningful increase in median body weight when compared to placebo. 60 mg of ITI-007 was not statistically significantly different from placebo in the proportion of patients with a =7% increase in body weight from baseline, consistent with a favorable body weight and metabolic profile.

Cardiovascular safety and prolactin levels: At 60 mg and 120 mg ITI-007 showed a favorable cardiovascular side effect profile. Unlike risperidone, ITI-007 did not show sustained increase in heart rate.

Unlike risperidone ITI-007 did not increase prolactin levels from baseline. In the study, ITI-007 demonstrated statistically significantly lower plasma prolactin levels compared to risperidone.

The Company believes ITI-007 has demonstrated a favorable safety and tolerability profile when compared to risperidone in the ITI-007-005 trial. The Company also believes that the profile of ITI-007 on measures related to movement disorders, metabolic, prolactin or cardiovascular signals compares favorably to other marketed antipsychotics.

Tomorrow, May 7, Jeffrey A. Lieberman, M.D., President, American Psychiatric Association; Lawrence C. Kolb Professor and Chairman of Psychiatry at the Columbia University College of Physicians and Surgeons, and Director of the New York State Psychiatric Institute, will present a summary of the ITI-007-005 trial results in an oral presentation.

About the ITI-007-005 Phase 2 Clinical Trial Design

The Phase 2 clinical trial, ITI-007-005, was a randomized, double-blind, placebo- and active-controlled clinical trial in patients with an acutely exacerbated episode of schizophrenia. In this trial, 335 patients were randomized to receive one of four treatments: 60 mg ITI-007, 120 mg ITI-007, 4 mg risperidone (active control) or placebo in a 1:1:1:1 ratio. Patients received study treatment orally once daily in the morning for 28 days. Of those randomized, 311 patients were included in the intent-to-treat primary analysis.

The primary endpoint for this clinical trial was change from baseline to Day 28 on the 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. Safety and tolerability were also assessed.

About Intra-Cellular Therapies

Intra-Cellular Therapies (the “Company”) is developing novel drugs for the treatment of neuropsychiatric and neurodegenerative disease and other disorders of the central nervous system (“CNS”). The Company is developing its lead drug candidate, ITI-007, for the treatment of schizophrenia, behavioral disturbances in dementia, bipolar disorder and other neuropsychiatric and neurological disorders. In December 2013, the Company announced positive topline results from the Company’s randomized, placebo- and active-controlled Phase 2 clinical trial of ITI-007 in patients with acutely exacerbated schizophrenia. This study showed a statistically significant improvement in symptoms associated with schizophrenia at the 60 mg dose on the trial’s pre-specified primary endpoint and a favorable safety profile. The Company is exploring lower doses of ITI-007 for the treatment of behavioral disturbances in dementia and related disorders. ITI-007 is in a Phase 1/2 safety, tolerability and pharmacokinetic clinical study in elderly patients and in geriatric subjects with and without dementia. The Company is also utilizing its phosphodiesterase (“PDE”) platform and other proprietary chemistry platforms to develop drugs for the treatment of cognitive deficits in schizophrenia and other CNS disorders. The Company has partnered its lead PDE1 compound, ITI-214, and backups from this platform with the Takeda Pharmaceutical Company. ITI-214 has finished the first Phase 1 clinical trial and is now in subsequent Phase 1 trials. The Company is also developing inhibitors against additional targets for CNS indications such as Alzheimer’s disease, Parkinson’s disease and depression and non-CNS indications such as cardiovascular disease.

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 belief that the profile of ITI-007 on measures related to movement disorders, metabolic, prolactin or cardiovascular signals compares favorably to other marketed antipsychotics. 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 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 and commercialization 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, 2013 filed with the Securities and Exchange Commission, as well as any updates to those risk factors filed from time to time in our periodic and current reports. 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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