May 18, 2016

Intra-Cellular Therapies presents at the Annual Meetings of the Society of Biological Psychiatry and the American Psychiatric Association

NEW YORK, May 18, 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 presented posters related to ITI-007, the Company's lead product candidate, at the 2016 Society of Biological Psychiatry (SOBP) Annual Meeting and the 2016 American Psychiatric Association (APA) Annual Meeting.

The poster presentations featured additional data from the Company's previously reported two positive ITI-007 schizophrenia clinical studies.

SOBP poster #1036 entitled: "Unique Pharmacology of ITI-007 Confers Efficacy in the Treatment of Schizophrenia at Low Striatal D2 Receptor Occupancy Levels" was presented on May 14th.

APA poster #P6-146 entitled: "ITI-007 for the Treatment of Schizophrenia: Primary & Secondary Efficacy Endpoints and Subgroup Analyses from Two Positive Randomized, Double-Blind, Placebo-Controlled Trials," was presented on May 16th.

Two positive ITI-007 clinical trials, the Company's Phase 3 Study ‘301 and Phase 2 Study ‘005, in schizophrenia have been completed. In both trials, ITI-007 60 mg demonstrated antipsychotic efficacy as measured by change in the Positive and Negative Syndrome Scale (PANSS) total score versus placebo at study endpoint. ITI-007 required no dose titration, showed early onset and sustained efficacy. ITI-007 was well-tolerated with a placebo-like safety profile.

A pooled efficacy analysis from Studies ‘301 and ‘005 was presented for ITI-007 60 mg. The pooled analysis confirmed efficacy of ITI-007 in patients with schizophrenia. This dose of ITI-007 was statistically significantly superior to placebo as early as week 1, with continued superiority to placebo demonstrated through the last study endpoint on Day 28 (p=0.0002; ES: 0.359).

APA poster #P6-147 entitled: "ITI-007 for the Treatment of Schizophrenia: Safety & Tolerability Data to Date from Two Double-Blind, Randomized, Placebo-Controlled Clinical Trials," was presented on May 16th.

In the Company's Phase 3 Study ‘301 and Phase 2 Study ‘005, ITI-007 was well-tolerated with a placebo-like safety profile. The most frequent treatment-emergent adverse events occurring in both studies and considered at least possibly related to ITI-007 were predominantly mild sedation/somnolence. In addition, ITI-007 demonstrated a motoric and metabolic profile similar to placebo.

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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