Intra-Cellular Therapies Announces Presentations on Lumateperone at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting

May 29, 2018

NEW YORK, May 29, 2018 (GLOBE NEWSWIRE) -- Intra-Cellular Therapies, Inc. (Nasdaq:ITCI), a biopharmaceutical company focused on the development of therapeutics for central nervous system (CNS) disorders, announced poster presentations at the upcoming American Society of Clinical Psychopharmacology (ASCP) Annual Meeting in Miami, Florida May 29-June 1, 2018.

A poster presentation (W54) entitled, “Lumateperone Improves Negative Symptoms Related to Emotional Experience (Avolition) in Patients with Schizophrenia” is being presented Wednesday, May 30, 2018, 11:15 am - 1:00 pm ET. This poster will be presented by Dr. Philip D. Harvey, Leonard M. Miller Professor of Psychiatry and Behavioral Sciences at the University of Miami Miller School of Medicine.

A poster presentation (T54) entitled, “A Novel Approach to Address an Unmet Need in the Treatment of Schizophrenia and Depression: Lumateperone, an Innovative Modulator of Dopamine, Serotonin, and Glutamate” is being presented Thursday, May 31, 2018, 12:30 pm - 2:00 pm ET. This poster will be presented by Dr. Kimberly E. Vanover, Senior Vice President of Clinical Development, Intra-Cellular Therapies.

A poster presentation (T35) entitled, “Project STARR 911: A Model for Researchers to Engage in Suicide Prevention” is being presented Thursday, May 31, 2018, 12:30 pm - 2:00 pm ET. This poster presentation is the result of an initiative by stakeholders within the STARR Coalition, including Intra-Cellular Therapies. Intra-Cellular Therapies is proud to be among the co-authors including representatives of the pharmaceutical industry, contract research organizations, clinical sites and patient advocacy groups.

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, lumateperone (also known as 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. Lumateperone, 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 (PDE) platform and other proprietary chemistry platforms to develop drugs for the treatment of CNS and other disorders. The lead molecule in the Company's PDE1 portfolio, ITI-214, is in development for the treatment of symptoms associated with Parkinson's disease and for the treatment of heart failure.

About Lumateperone for the Treatment of Schizophrenia

Lumateperone, our lead product candidate, is a first-in-class molecule that provides selective and simultaneous modulation of serotonin, dopamine, and glutamate - three neurotransmitter pathways implicated in severe mental illness. Unlike existing schizophrenia treatments, lumateperone is a dopamine receptor phosphoprotein modulation, or DPPM, acting as a pre-synaptic partial agonist and post-synaptic antagonist at D2 receptors. We believe this mechanism, along with potent interactions at 5-HT2A receptors, serotonin transporters, and D1 receptors with indirect glutamatergic modulation, may contribute to the efficacy of lumateperone across a broad array of symptoms, with improved psychosocial function and favorable tolerability. This compound has the potential to benefit patients suffering from a range of neuropsychiatric and neurodegenerative diseases.

Our clinical development program for the treatment of schizophrenia with lumateperone includes three large randomized, double-blind, placebo-controlled trials. In two studies, ITI-007 60 mg showed a statistically significant separation from placebo on the primary endpoint, the Positive and Negative Syndrome Scale, or PANSS, total score. Across all three studies, lumateperone was found to be well tolerated with a safety profile similar to placebo.

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, the progress and results of our clinical trials and preclinical studies; the safety and efficacy of our product development candidates; our beliefs about the potential uses and benefits of our drug product candidates; 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 lumateperone, 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:

Intra-Cellular Therapies, Inc.
Juan Sanchez, M.D.
Vice President, Corporate Communications and Investor Relations
646-440-9333

Burns McClellan, Inc.
Lisa Burns
Justin Jackson (Media)
jjackson@burnsmc.com

212-213-0006

Primary Logo

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