Intra-Cellular Therapies Presents Data on Mechanism of Action of Lumateperone and ITI-214 at the 2017 Society for Neuroscience (SfN) Annual Meeting

November 14, 2017

NEW YORK, Nov. 14, 2017 (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 poster presentations related to its lumateperone and ITI-214 development programs at the 2017 Society for Neuroscience Annual Meeting (SfN) being held in Washington DC, November 11-14.

Poster # 511.18 entitled “Lumateperone (ITI-007) is a postsynaptic D2 receptor antagonist” is being presented Tuesday November 14, 2017 during the Poster Session – Striatal Circuits in Behavior.

In this poster we present preclinical data detailing the unique mechanism of action of lumateperone at the D2 receptor, further characterizing the pharmacology of this first-in-class investigational agent. This finding strengthens our understanding of the unique mechanism of action of lumateperone as a pre-synaptic D2 partial agonist and a post-synaptic D2 antagonist, which is believed to form the basis of efficient modulation of dopamine, providing antipsychotic efficacy at relatively low striatal D2 receptor occupancy without the motor disturbances associated with many current antipsychotic therapies.

Poster #564.23 entitled “ITI-214, a novel and selective phosphodiesterase 1 inhibitor, reverses LPS-induced inflammatory responses in BV2 cells and in mice” is being presented Tuesday November 14, 2017 during the Poster Session– Microglia in Disease.

In this presentation we describe preclinical data showing the importance of ITI-214 and inhibition of PDE1 in reducing neuroinflammation, and in regulating microglial function, the primary immune cells of the CNS. Specifically, ITI-214 suppressed proinflammatory responses in vivo in a mouse model of inflammation and in vitro in mouse microglial cells. Reflecting the dual roles for the molecular target of ITI-214, PDE1, both cGMP-dependent and cAMP-dependent intracellular pathways were involved in the anti-inflammatory response. These data support a unique role for ITI-214 in regulating microglial responses and its use in treating neuroinflammation.

Excessive inflammation has been implicated in neurodegenerative diseases, where neurons are lost and not replaced. Microglia, the resident immune cells in the nervous system, express both anti-inflammatory and proinflammatory phenotypes, and understanding the mechanisms that control the expression of these phenotypes may provide new avenues for therapeutic intervention in neurodegenerative disease.

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.

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 and preclinical studies; our beliefs about the extent to which the results of our clinical trials and preclinical studies to date support new drug application filings for lumateperone; 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.

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