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Intra-Cellular Therapies Presents Data Supporting the Potential for Potent and Rapid Antidepressant Activity with Lumateperone

NEW YORK, May 08, 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 it had two presentations on its novel investigational agent lumateperone at the 19th Annual Conference of the International Society for Bipolar Disorders (ISBD) held in Washington, DC, May 4-7, 2017.

The Company's presentations at ISBD focused on the unique pharmacology of lumateperone and included both preclinical and clinical data supporting its development for the treatment of bipolar depression. Specifically, previous results in the Company's schizophrenia efficacy studies found robust improvements in depressive as well as psychotic symptoms for those patients who were comorbidly depressed at baseline. Further, new preclinical data demonstrate that lumateperone, as a standalone agent, uniquely potentiates both AMPA and NMDA glutamate neurotransmission in the prefrontal cortex, mechanisms thought to predict potent and rapid antidepressant effects. These effects on glutamate neurotransmission are dependent on the ability of lumateperone to simultaneously increase D1 receptor activity and inhibit SERT activity. The Company has also recently demonstrated that lumateperone regulates phosphorylation of key proteins in the mTOR pathway, similar to ketamine which has shown rapid antidepressant effects, yet lumateperone has not been associated with ketamine-like safety concerns. In over 1500 individuals exposed to date in clinical trials, lumateperone has been well-tolerated with a safety profile similar to placebo. These exciting findings, in addition to the potent SERT activity previously described with lumateperone, suggest the potential for lumateperone to exhibit potent and rapid antidepressant effects in patients suffering from a range of mood disorders including bipolar depression, major depressive disorder (MDD) and treatment-resistant depression (TRD). Further clinical evaluation for mood disorders, in addition to the ongoing Phase 3 lumateperone bipolar depression trials, is warranted.

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 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 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 lumateperone; 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