Intra-Cellular Therapies to Present Data on Lumateperone and ITI-333 at the 58th Annual Meeting of the American College of Neuropsychopharmacology

December 4, 2019

NEW YORK, Dec. 04, 2019 (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 that the Company will be presenting at the 58th Annual Meeting of the American College of Neuropsychopharmacology (ACNP) to be held in Hollywood, FL, December 8-11, 2019.

Intra-Cellular Therapies will be presenting the following posters and presentations at ACNP, which will include results from Study 404, a Phase 3 clinical trial evaluating lumateperone for the treatment of bipolar depression, as well as new data from the schizophrenia clinical program including the long-term safety study. Lumateperone is a novel investigational drug currently under review by the FDA as a potential treatment for adults with schizophrenia. Preclinical data on ITI-333, our novel compound with high affinity at serotonin 5-HT2A, dopamine D1 and mu opioid (MOP) receptors for the potential treatment of substance use disorders and pain will also be presented.

Oral Presentation

Tuesday, December 10, 2019, 4:55 pm – 5:30 p.m. ET during panel “Responses to the Opioid Epidemic: Government, Industry and Academic Perspectives”.

- “ITI-333: An Investigational Drug for the Treatment of Opioid Use Disorder”. Presented by Kimberly Vanover Ph.D., Senior Vice President, Translational Medicine and Early Stage Clinical Development, at ITCI.

Wednesday, December 11, 2019, 5:30 pm - 7:30 p.m. ET during Poster Session III.

- “Lumateperone (ITI-007) in the Treatment of Bipolar Depression: Results from a Randomized Clinical Trial” (Poster W123). Authors include: S. Durgam; A. Satlin; K. Vanover; R. Davis; S. Kozauer; R. Chen; S. Mates; J. R. Calabrese.
- “Additional Results from a 12-Month Open-Label Safety Study of Lumateperone (ITI-007) in Patients with Stable Symptoms of Schizophrenia” (Poster W203). Authors include: A. Satlin; K. Vanover; S. Durgam; S. Mates; R. Davis; C. Correll.
- “Efficacy and Safety of Lumateperone 42 mg in the Treatment of Schizophrenia: A Pooled Analysis of Randomized Clinical Trials” (Poster W 201). Authors include: K. Vanover; J. Kane; A. Satlin; S. Durgam; R. Davis; S. Mates; C. Correll; C. Tamminga.

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 is under review by the FDA for the treatment of schizophrenia and is in Phase 3 clinical development for the treatment of bipolar depression. 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.

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 safety and efficacy of our product development candidates; the potential for lumateperone to benefit patients suffering from a range of neuropsychiatric and neurodegenerative diseases 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: whether the NDA for lumateperone for the treatment of schizophrenia will be approved by the FDA and whether the FDA will complete its review within the target timelines; the risk that the NDA will not be approved despite the FDA's acceptance of the NDA for review or that the FDA will require additional information; risks associated with our current and planned clinical trials; we may encounter unexpected safety or tolerability issues with lumateperone in ongoing or future trials and other development activities; 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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