# Intra-Cellular Therapies Announces Presentations on Lumateperone Schizophrenia Program at the American Psychiatric Association (APA) Annual Meeting

May 15, 2019

NEW YORK, May 15, 2019 (GLOBE NEWSWIRE) -- Intra-Cellular Therapies, Inc. (Nasdaq:ITCI), a biopharmaceutical company focused on the development of therapeutics for central nervous system (CNS) disorders, announced the presentation of posters highlighting the lumateperone program in schizophrenia at the 2019 American Psychiatric Association (APA) Annual Meeting in San Francisco, May 18-22, 2019. Lumateperone is a novel investigational drug currently under review by the FDA as a potential treatment for adults with schizophrenia.

The upcoming presentations at APA highlight the lumateperone clinical program in schizophrenia with posters showing lumateperone's clinical results including its favorable safety and tolerability profile documented in the program

The titles of the poster presentations are as follows:

Tuesday, May 21, 2019, 10:00 a.m.-12:00 p.m. PT

- "The Efficacy of Lumateperone 42mg in the Treatment of Schizophrenia: A Pooled Analysis of Randomized Controlled Trials" (P7-067). The lead author is Carol Tamminga, MD, Lou and Ellen McGinley Distinguished Chair in Psychiatric Research at the University of Texas Southwestern Medical School.

- "The Safety and Tolerability of Lumateperone 42mg for the Treatment of Schizophrenia: A Pooled Analysis of 3 Randomized Placebo-Controlled Trials" (P7-04). The lead author is John M Kane, MD, Chairman Department of Psychiatry at the Zucker Hill Hospital and the Donald and Professor & Chair, Psychiatry at the Barbara Zucker School of Medicine at Hofstra/Northwell.

**About Lumateperone for the Treatment of Schizophrenia**

Lumateperone, our lead product candidate, is a molecule that provides selective and simultaneous modulation of serotonin, dopamine, and glutamate - three neurotransmitter pathways implicated in severe mental illness. Lumateperone is a potent serotonin 5-HT2A receptor antagonist, a dopamine receptor phosphoprotein modulator (DPPM) acting as a presynaptic partial agonist and postsynaptic antagonist at dopamine D2 receptors, a dopamine D1 receptor-dependent indirect modulator of glutamate (both NDMA and AMPA), and a serotonin reuptake inhibitor. This compound has the potential to benefit patients suffering from a range of neuropsychiatric and neurodegenerative diseases.

**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. Intra-Cellular Therapies 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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