

Intra-Cellular Therapies Announces Presentation of Lumateperone Long-term Open Label Safety Study at the 2019 Congress of the Schizophrenia International Research Society

April 9, 2019

NEW YORK, April 09, 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 plans to present analyses from its open-label safety switching study (Study 303) assessing the effects of long-term administration of lumateperone in patients with stable symptoms of schizophrenia at the upcoming 2019 Congress of the Schizophrenia International Research Society being held in Orlando, Florida April 10-14, 2019.

Poster #S117 entitled "Favorable Long-Term Safety Profile of Lumateperone (ITI-007): Results from a 12-Month Open Label Safety Study in Patients with Stable Symptoms of Schizophrenia" will be presented on Saturday April 13th 12:00-2:00 pm ET during Poster Session III.

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-HT_{2A} 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 NMDA 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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