Intra-Cellular Therapies Initiates Rolling Submission of New Drug Application for Lumateperone for Treatment of Schizophrenia

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NEW YORK, June 06, 2018 (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 the initiation of a rolling submission of its New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for lumateperone for the treatment of schizophrenia. The Company plans to complete this NDA submission in mid-2018.

In 2017 the FDA granted Fast Track designation for lumateperone for the treatment of schizophrenia. The Company requested Fast Track designation for lumateperone based on clinical evidence that lumateperone has the potential to address unmet medical needs for the treatment of schizophrenia. The FDA's Fast Track designation is designed to facilitate the development and expedite the review of drug candidates to treat serious and life-threatening conditions.

"We are excited to have initiated our NDA filing for lumateperone for the treatment of schizophrenia, which is an important milestone in our mission to bringing innovative treatments to patients suffering from neuropsychiatric conditions," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "We believe lumateperone, with its unique pharmacology and existing clinical profile, potentially represents an important advance in the treatment of patients with schizophrenia."

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 and for the treatment of heart failure.

About Lumateperone for the Treatment of Schizophrenia

Lumateperone, our lead product candidate, is a first-in-class molecule that provides selective and simultaneous modulation of serotonin, dopamine, and glutamate - three neurotransmitter pathways implicated in severe mental illness. Unlike existing schizophrenia treatments, lumateperone is a dopamine receptor phosphoprotein modulation, or DPPM, acting as a pre-synaptic partial agonist and post-synaptic antagonist at D2 receptors. We believe this mechanism, along with potent interactions at 5-HT2A receptors, serotonin transporters, and D1 receptors with indirect glutamatergic modulation, may contribute to the efficacy of lumateperone across a broad array of symptoms, with improved psychosocial function and favorable tolerability. This compound has the potential to benefit patients suffering from a range of neuropsychiatric and neurodegenerative diseases.

Our clinical development program for the treatment of schizophrenia with lumateperone includes three large randomized, double-blind, placebo-controlled trials. In two studies, ITI-007 60 mg showed a statistically significant separation from placebo on the primary endpoint, the Positive and Negative Syndrome Scale, or PANSS, total score. Across all three studies, lumateperone was found to be well tolerated with a safety profile similar to placebo.

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 initiation of a rolling NDA for lumateperone for the treatment of schizophrenia and our expectations about the timing of the completion of such NDA submission by mid-2018; our belief that lumateperone has the potential to represent an important advance in the treatment of patients with schizophrenia; the potential benefits of Fast Track designation to facilitate or accelerate the regulatory approval of lumateperone for the treatment of schizophrenia; 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: 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, 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; fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process; 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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