Intra-Cellular Therapies Receives FDA Fast Track Designation for Lumateperone for the Treatment of Schizophrenia

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NEW YORK, Nov. 20, 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 that the U.S. Food and Drug Administration (FDA) has 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 the unmet medical need for the treatment of schizophrenia with significant improvements on several clinically significant safety parameters, including with respect to metabolic, motor and cardiovascular issues associated with many currently available antipsychotic agents. 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. Fast Track designation may allow for more frequent meetings and communications with the FDA to discuss a drug candidate's development plans and review process. Drug candidates with Fast Track designation may also qualify for priority review to expedite the FDA review process, if relevant criteria are met.

"We are pleased with the FDA's designation of lumateperone for Fast Track development," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "Given the important safety and tolerability limitations of existing antipsychotics, we believe that lumateperone may represent a significant advance in the treatment of schizophrenia."

About Schizophrenia

Schizophrenia is a chronic debilitating psychiatric disorder that affects over 1% of the world's population. There remains a substantial unmet medical need for the treatment of schizophrenia. Existing treatments, while helpful for reducing the positive symptoms of schizophrenia, do not provide broad symptom control across other symptom domains and are limited in their use due to side effects that can include movement disorders, weight gain, metabolic disturbances, and cardiovascular abnormalities, all of which lead to poor medication adherence. Further, it has been demonstrated that poor adherence to antipsychotics is associated with higher risk of relapse, rehospitalization and increased healthcare costs.

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, ITI-007 was found to be well tolerated with a safety profile similar to placebo.

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.

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 belief that lumateperone has the potential to address an unmet medical need for the treatment of schizophrenia, the potential benefits of Fast Track designation to facilitate or accelerate the regulatory approval of lumateperone for the treatment of schizophrenia, including the potential for more frequent meetings with the FDA and the potential qualification of lumateperone for priority review, our belief that lumateperone may represent a significant advance in the treatment of schizophrenia, our beliefs about the limitations of existing treatments for schizophrenia, our beliefs about the mechanisms of action of ITI-007; our beliefs about the extent to which the results of our clinical trials to date support an NDA filing for lumateperone for the treatment of schizophrenia; our expectations regarding our timelines for submitting an NDA to the FDA for the treatment of schizophrenia; our belief that lumateperone, if approved, will be an attractive treatment option for schizophrenia; our beliefs about the potential uses and benefits of our drug product candidates; 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; the Fast Track designation may not lead to an expedited development, review or approval process and does not increase the likelihood that lumateperone will receive regulatory approval; the Fast Track designation may be rescinded by the FDA if the designation is no longer supported by data emerging in the clinical trial process; 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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