Intra-Cellular Therapies Provides Lumateperone Regulatory Update

September 10, 2019

FDA has informed the Company it has no plans to schedule an Advisory Committee Meeting

Company has completed submission of non-clinical information previously agreed with FDA

NEW YORK, Sept. 10, 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 U.S. Food and Drug Administration (FDA) has informed the Company that it does not have plans to schedule an Advisory Committee meeting in connection with its review of the Company's New Drug Application (NDA) for lumateperone for the treatment of schizophrenia. The lumateperone Prescription Drug User Fee Act (PDUFA) goal date is December 27, 2019.

Additionally, the Company recently submitted to the FDA the results of non-clinical analyses the Company previously announced it had agreed to conduct related to toxicology findings in animal studies. The Company believes the results of these analyses provide additional support for its position that the metabolic pathway, and the metabolites formed, are different in animals and humans and therefore toxicity findings in animals are not relevant to humans.

"We have been working diligently to address the FDA requests for information and are optimistic that the additional non-clinical information we submitted addresses those requests," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "There is an ongoing unmet need for new treatments for schizophrenia and we look forward to continuing our work with the FDA to bring lumateperone to patients."

About Lumateperone

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. Lumateperone is an investigational new drug and has not been approved for marketing for any use by the FDA or any other regulatory authority in any other jurisdiction.

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, tolerability and efficacy of our product candidates; the PDUFA goal date for the FDA's review of the lumateperone NDA; the FDA's indication that it has no plans to schedule an Advisory Committee meeting; our belief that the results of the analyses conducted provide additional support for its position that those findings are not relevant to humans; our belief that the analyses conducted further confirm that the metabolic pathway, and the metabolites formed, are different in animals and humans; our belief that the additional non-clinical information we submitted to the FDA addresses the FDA requests; the potential for lumateperone to provide benefits in a broad range of neuropsychiatric conditions; 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, including the PDUFA goal date; the risk that the NDA will not be approved despite the FDA's acceptance of the NDA for review; whether the FDA will require additional information, whether we will be able to provide in a timely manner any additional information that the FDA requests, and whether such additional information will be satisfactory to the FDA; the possibility that the FDA re-evaluates its plans not to schedule an Advisory Committee meeting and the risk that any such Advisory Committee meeting will negatively impact the approval of the NDA for lumateperone; 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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