

Intra-Cellular Therapies Announces FDA Advisory Committee Meeting to Review the NDA for Lumateperone for the Treatment of Schizophrenia in Adults

June 13, 2019

NEW YORK, June 13, 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 announced a Psychopharmacologic Drugs Advisory Committee meeting to be held on July 31, 2019 to discuss the New Drug Application (NDA) for lumateperone with the proposed indication of treatment of schizophrenia in adults. Lumateperone is a novel investigational drug with an NDA currently under review by FDA as a treatment of schizophrenia in adults.

FDA's expected Prescription Drug User Fee Act (PDUFA) action date is September 27, 2019.

"There remains a significant unmet medical need in the treatment of schizophrenia," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "We welcome the opportunity to present our data at the Advisory Committee meeting as we continue working to bring lumateperone to patients living with this debilitating disease."

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 is being investigated in 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. The NDA for 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; the risk that the 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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