Intra-Cellular Therapies Provides Update on FDA Advisory Committee Meeting for Lumateperone for the Treatment of Schizophrenia

July 23, 2019

NEW YORK, July 23, 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 cancelled the Psychopharmacologic Drugs Advisory Committee meeting scheduled for July 31, 2019 to discuss the New Drug Application (NDA) for lumateperone for the treatment of schizophrenia.

The Company recently provided additional information to the FDA in response to information requests relating to non-clinical studies. The FDA cancelled the Advisory Committee meeting to allow sufficient time to review this new and any forthcoming information as they continue the NDA review. This information may result in an extension of the September 27, 2019 Prescription Drug User Fee Act (PDUFA) target action date for the lumateperone NDA.

The Company has a meeting scheduled with the FDA shortly and will provide an update following the meeting.

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 U.S. Food and Drug Administration (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 target action date for the FDA's review of the lumateperone NDA; our plans to provide an update following our meeting with the FDA; 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 any new PDUFA target action 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 risk that a future 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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