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Intra-Cellular Therapies Announces Positive Regulatory Update On Schizophrenia Program

Following FDA interactions Company moving forward with long-term safety study of lumateperone and preparing for NDA submission for the treatment of schizophrenia by mid-2018

NEW YORK, Aug. 23, 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 informed the Company that the FDA (i) has completed its review of the Company's responses to requests from the FDA for additional information relating to certain findings observed in nonclinical toxicology studies of lumateperone in an animal species and (ii) agrees that the Company has presented adequate data to support its position that the metabolic pathway in the animal species is distinctive from humans, which indicates that the toxicity observed in the animal species is not relevant to humans.

Accordingly, the Company is moving forward with its long-term safety study of lumateperone and intends to submit a new drug application (NDA) for the treatment of schizophrenia by mid-2018.

The Company previously announced that the FDA had raised questions relating to certain findings observed in nonclinical toxicology studies of lumateperone in an animal species and requested additional information to confirm that the nonclinical findings are not indicative of a safety risk associated with long term exposure in humans. The data presented by the Company supports the position that there are significant species differences in the metabolism of lumateperone. Based on the FDA's agreement that the Company presented adequate data indicating that the toxicity seen in the animal species is not relevant to humans, the Company is proceeding with its long-term safety study of lumateperone in patients with schizophrenia. Further, based on feedback from the FDA, the Company will incorporate additional monitoring in its long-term safety study for metabolites seen in animal species but not seen to date in humans, and also will continue to monitor for toxicities in its nonclinical studies. With over 1,500 people exposed to date, lumateperone has been well-tolerated with a safety profile similar to placebo.

"We are very pleased with the outcome of our discussions with the FDA and look forward to progressing our schizophrenia program," said Dr. Sharon Mates, Chairman and CEO of ITCI.

The Company previously announced that it had requested guidance from the FDA on the acceptability of the two positive well-controlled clinical trials it has conducted (Study ITI-007-005 and Study ITI-007-301), with supportive evidence from Study ITI-007-302, as the basis for the submission of an NDA for the treatment of schizophrenia. As previously disclosed, the FDA has confirmed that the results of Study ITI-007-302 do not preclude the Company from submitting an NDA based on the efficacy studies it has conducted to date and the Company intends to submit an NDA for lumateperone for the treatment of schizophrenia supported by the efficacy studies it has conducted to date. Efficacy is supported by two positive large, randomized, double-blind, placebo-controlled US-based clinical studies at a fixed dose of lumateperone (ITI-007 60 mg) with no dose titration required. Across all three short-term efficacy studies the magnitude and trajectory of improvement with ITI-007 60 mg was similar. Additionally, supportive data provide evidence of pharmacological activity and clinical benefit of ITI-007 40 mg. Moreover, lumateperone has been well-tolerated, with a safety profile similar to placebo across all clinical studies conducted to date, and with clinically relevant and statistically significant safety and tolerability advantages when directly compared in two studies with risperidone used as an active control, the most commonly prescribed antipsychotic for the treatment of schizophrenia. These advantages include no significant adverse effects on cardiovascular parameters, weight, lipids, glucose, prolactin and motor function. Given the safety and tolerability limitations of existing antipsychotics (e.g., cardiovascular abnormalities, metabolic dysregulation and motor disturbances), the Company believes lumateperone, if approved, will be an attractive treatment option for physicians and their patients with schizophrenia.

To address long term safety and to observe the impact of switching from standard-of-care antipsychotic medications, the Company is conducting an open-label safety study in stable patients with schizophrenia switched to lumateperone (ITI-007 60 mg) from standard of care antipsychotic therapy. This study is being conducted in two parts. The first part has completed clinical conduct and included a 6-week treatment duration with lumateperone followed by a 2-week period where patients are switched back to standard-of-care. This study assesses both the impact of switching to lumateperone from standard-of-care antipsychotics as well as the impact of switching back to standard-of-care antipsychotics from lumateperone. Topline data from the first part of the study will be available shortly. The second part of the study, the Company's long-term safety study in schizophrenia, is enrolling additional patients for up to 1 year treatment duration.

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 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 the toxicity findings observed in nonclinical animal toxicology studies of lumateperone are not indicative of a safety risk for humans; our belief that our monitoring in our ongoing long-term safety study and nonclinical studies will not impact our timelines for filing an NDA for lumateperone for the treatment of schizophrenia; our belief that lumateperone, if approved, will be an attractive treatment option for 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: any toxicities discovered in our long-term safety study of lumateperone in patients with schizophrenia and nonclinical studies could delay or prevent our filing of an NDA; the FDA may place our long-term safety study on a clinical hold, which would delay or prevent us from completing the safety study and from filing an NDA; 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; 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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