Intra-Cellular Therapies Announces Presentations on Lumateperone at Two Upcoming Medical Conferences

May 4, 2018

NEW YORK, May 04, 2018 (GLOBE NEWSWIRE) -- Intra-Cellular Therapies, Inc. (Nasdaq:ITCI), a biopharmaceutical company focused on the development of therapeutics for central nervous system (CNS) disorders, announced presentations on lumateperone at the 2018 American Psychiatric Association (APA) Annual Meeting in New York, May 5-9, 2018, and at the Society of Biological Psychiatry (SOBP) Annual Meeting in New York, May 10-12, 2018.

APA Annual Meeting in New York, May 5-9, 2018

A poster presentation (P5-178) entitled “Lumateperone (ITI-007) for the Treatment of Schizophrenia: Overview of Placebo-Controlled Clinical Trials and an Open-Label Safety Switching Study” is being presented Monday, May 7, 2018, 10:00 am - 12:00 pm ET during Poster Session 5.

The presentation highlights key findings from the lumateperone clinical development program in schizophrenia. The schizophrenia efficacy program includes two positive randomized, double-blind, placebo-controlled trials and supportive data from a third study, all three conducted in the United States. A 6-week safety switching study in patients with stable symptoms of schizophrenia was also performed. With over 2,000 people exposed to lumateperone to date, the Company believes the data generated to-date provide evidence of the efficacy and favorable safety profile of lumateperone for the treatment of schizophrenia.

A poster presentation (P6-155) entitled “Lumateperone (ITI-007): Results From an Open-Label Safety Switching Study From Standard-of-Care Antipsychotic Therapy in Patients With Schizophrenia” is being presented Monday, May 7, 2018, 2:00 pm - 4:00 pm ET during Poster Session 6.

The poster presents additional information from the ITI-007-303 lumateperone open-label safety switching study. This study extends our understanding of the safety and effectiveness of lumateperone. Patients (N=302) with stable symptoms of schizophrenia were switched from standard-of-care antipsychotic medications to lumateperone with no dose titration required for a 6-week treatment duration, then switched back to standard-of-care and assessed again after 2 weeks. Consistent with and extending previous data from our studies in patients with acutely exacerbated schizophrenia, lumateperone (ITI-007 60 mg) was generally well-tolerated with a favorable safety profile. Statistically significant improvements from standard-of-care baseline were observed in body weight, cardiometabolic and endocrine parameters in patients with stable symptoms of schizophrenia when switched to lumateperone, and several of these safety parameters worsened again when switched back to standard-of-care medication. Additionally, treatment with lumateperone was not associated with the motor or cardiovascular disturbances often associated with other antipsychotic medications. In this study symptoms of schizophrenia did not worsen upon switch to lumateperone. Rather, statistically significant improvement from baseline was observed in the Positive and Negative Syndrome Scale (PANSS) mean total score. In addition, greater improvements were observed in subgroups of patients with comorbid symptoms of depression and those with prominent negative symptoms.

SOBP Annual Meeting in New York, May 10-12, 2018:

A poster presentation (S81) entitled “Unique Pharmacology and Clinical Evidence Supporting the Antidepressant Therapeutic Potential of Lumateperone” is being presented Saturday, May 12, 2018, 5:00 pm - 7:00 pm ET during Poster Session 3.

This presentation highlights preclinical and clinical data that support the use of lumateperone in depressive disorders.

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 and for the treatment of heart failure.

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, lumateperone was found to be well tolerated with a safety profile similar to placebo.

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 therapeutic value, clinical and non-clinical development plans and commercial potential of our drug product candidates; the progress, timing and results of our clinical trials and

preclinical studies; our beliefs about the extent to which the results of our clinical trials and preclinical studies to date support new drug application filings for product candidates; the safety and efficacy of our product development candidates; 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: this switching study was an open label study and its efficacy observations may not be replicated in any future controlled trials; 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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