Intra-Cellular Therapies Presents Data on Symptom Improvement by Lumateperone on Negative Symptoms, Depression, and Social Function in Patients with Schizophrenia at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting

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NEW YORK, May 31, 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 American Society of Clinical Psychopharmacology (ASCP) Annual Meeting in Miami, Florida May 29-June 1, 2018.

One of the Company's presentations at ASCP focused on the effect of lumateperone on a specific domain of negative symptoms of schizophrenia known to correlate with social function. The other presentation addressed the potential of lumateperone to improve symptoms of depression in patients with schizophrenia. These presentations build on prior data and continue to support the Company's belief that the unique pharmacology of lumateperone can translate into an advancement in the treatment of schizophrenia.

"All negative symptoms do not have the same impact on functional outcomes and the domain of symptoms (emotional experience) improved by lumateperone are the most important predictors of social dysfunction in schizophrenia. The fact that lumateperone selectively improves these negative symptoms suggests the potential for improved social outcomes in people with schizophrenia," said Dr. Philip D. Harvey, Leonard M. Miller Professor of Psychiatry and Behavioral Sciences at the University of Miami Miller School of Medicine.

While positive symptoms such as hallucinations, delusions, and suspiciousness can be effectively addressed by existing antipsychotics, negative symptoms such as emotional withdrawal and co-morbid symptoms of depression are common in the disorder yet not effectively treated. Moreover, interpersonal relationships and social function remain challenging for many people living with schizophrenia. The Company believes that lumateperone has the potential to treat symptomatology known to favorably impact social function and, thereby, significantly improve quality of life and better allow individuals living with schizophrenia to reintegrate into society.

Lumateperone is a first-in-class antipsychotic currently in development for the treatment of schizophrenia. In the Company's schizophrenia program, lumateperone has demonstrated broad symptom control and has been well tolerated with a safety profile similar to placebo without the motor or cardiovascular disturbances often associated with other antipsychotic medications. Over 2,000 people have been exposed to lumateperone to date.

"There remains a significant medical need for safer and better tolerated medications which can improve the broad range of symptoms associated with schizophrenia and we are excited by the data we presented at ASCP and believe it further supports the potential of lumateperone to treat negative symptoms and depression and to improve social function," said Dr. Sharon Mates, Chairman and CEO of ITCI. "As we advance our precommercial activities for lumateperone for the treatment of schizophrenia, we continue to document the therapeutic profile of lumateperone to enable us to benefit patients and to guide our development strategy for the drug into additional therapeutic indications."

A poster presentation (W54) entitled "Lumateperone Improves Negative Symptoms Related to Emotional Experience (Avolition) in Patients with Schizophrenia" was presented Wednesday, May 30, 2018. This poster was presented by Dr. Philip D. Harvey, Leonard M. Miller Professor of Psychiatry and Behavioral Sciences at the University of Miami Miller School of Medicine.

The Positive and Negative Syndrome Scale (PANSS) is a well-validated tool for measuring multiple symptoms associated with schizophrenia. Negative symptoms as measured by the PANSS can be categorized into separable symptom domains related to emotional experience, also known as avolition, or related to emotional expression, also known as expressive deficit. Recent studies have shown that, among negative symptoms, the PANSS-derived symptom domain representing emotional experience highly correlates with interpersonal functioning. Emotional experience includes symptoms of passive social withdrawal, emotional withdrawal, and active social avoidance. When these symptoms are reduced, the motivation and ability to engage in interactions with other people improves.

Achieving gains in these deficits, which often remain after resolution of positive symptoms, is important for the long-term success of schizophrenia treatment, and is so far not addressed by available therapies. The data presented at ASCP included analyses from our schizophrenia studies ('301 and '005) showing that lumateperone selectively improves this critical negative symptom domain of emotional experience compared to placebo. Importantly, these results are consistent with previous data that demonstrated improved social function with lumateperone as measured by the Personal and Social Performance Scale.

A poster presentation (T54) entitled "A Novel Approach to Address an Unmet Need in the Treatment of Schizophrenia and Depression: Lumateperone, an Innovative Modulator of Dopamine, Serotonin, and Glutamate" is being presented Thursday, May 31, 2018. This poster is being presented by Dr. Kimberly E. Vanover, Senior Vice President of Clinical Development, Intra-Cellular Therapies.

In this presentation, higher levels of depression in two large cohorts of patients with schizophrenia were shown to be correlated with poor self-assessment of everyday functioning. Although depression does not worsen actual performance of day to day tasks, people with depression perceive themselves as performing worse. The high prevalence and severity of depression in patients with schizophrenia suggests that this is an area of considerable importance for therapeutic intervention. In separate studies testing lumateperone in patients with schizophrenia, we found reduced symptoms of depression and improved social function in addition to improvements in psychosis, particularly in patients with co-morbid depression. These improvements across broad symptom domains are predicted by lumateperone's unique pharmacological profile acting synergistically through serotonin, dopamine and glutamate. Lumateperone also has a favorable safety profile, and potentially represents a novel approach to the treatment of co-morbid depression and its consequences in a range of psychiatric 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, our belief that the unique pharmacology of lumateperone can translate into an advancement in the treatment of schizophrenia; our belief that lumateperone has the potential to treat symptomatology known to favorably impact social function and, thereby, significantly improve quality of life and better allow individuals living with schizophrenia to reintegrate into society; our belief in the potential of lumateperone to treat negative symptoms and depression, and to improve social function; 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: 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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