Intra-Cellular Therapies Presents Additional Results From Long-term Open Label Safety Study of Lumateperone at the 2019 Congress of the Schizophrenia International Research Society

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NEW YORK, April 15, 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 additional results from its open-label safety switching study (Study 303) assessing the effects of long-term administration of lumateperone, an investigational drug, in patients with stable symptoms of schizophrenia. Results were also presented on the improvements in symptoms of depression in patients with moderate to severe co-morbid depression. The data were presented at the 2019 Congress of the Schizophrenia International Research Society (SIRS), which was held in Orlando, Florida, April 10-14, 2019.

“Schizophrenia is a multidimensional illness with high rates of comorbidities, including depressive symptoms. Comorbid depression occurs in many patients with schizophrenia and is associated with high relapse rates and poor outcomes,” said Dr. Andrew Satlin, Executive Vice President and Chief Medical Officer of Intra-Cellular Therapies. “We previously presented pharmacologic evidence and clinical results from studies in patients with acutely exacerbated schizophrenia assessing the antidepressant potential of lumateperone. The long-term safety study results presented Saturday add to these prior findings by showing improvements in residual depressive symptoms in patients with otherwise stable symptoms of schizophrenia. Based on the totality of these findings, we believe lumateperone has the potential to provide antidepressant effects in patients suffering from a range of mood disorders, while offering the advantages of a favorable safety profile. Lumateperone is in Phase 3 development for the treatment of bipolar depression and we have commenced our clinical program in major depressive disorder as well.”

Poster #S117 entitled “Favorable Long-Term Safety Profile of Lumateperone (ITI-007): Results from a 12-Month Open Label Safety Study in Patients with Stable Symptoms of Schizophrenia” was presented on Saturday April 13th.

Study 303 was conducted to assess the long-term effects of treatment with lumateperone on weight and other safety parameters and to observe the impact of switching from standard-of-care (SOC) antipsychotic medications. The poster presented at SIRS provided additional detail on the initial results presented last year showing that lumateperone, administered for up to one year, was generally well tolerated and exhibited statistically significant improvements from baseline on key safety measures of body weight, cardiometabolic and endocrine parameters, without motor side effects often associated with other antipsychotic medications. In addition, patients treated with lumateperone remained stable with respect to their symptoms of schizophrenia upon switching from SOC.

Based on its pharmacology and prior clinical results we believe lumateperone may provide advantages in the treatment of the broad symptoms associated with schizophrenia including depressive symptoms. Thus, additional objectives of the study included determining the effectiveness of lumateperone at treating depressive symptoms in patients with co-morbid depression.

The antidepressant effects of lumateperone (ITI-007 60 mg) were assessed using the Calgary Depression Scale for Schizophrenia (CDSS), a validated scale to asses depression in patients with schizophrenia. In patients with moderate-to-severe depression symptoms at baseline (CDSS≥6; N=55), lumateperone treatment was associated with marked improvement in CDSS scores. Specifically, mean CDSS scores decreased by approximately 60% from 7.4 (baseline) to 3.1 (Day 300). In addition, 60% of patients met CDSS response criteria (50% improvement from baseline) by Day 75 and this response rate was maintained through Day 300. Importantly, a similar magnitude of CDSS improvement was seen regardless of concurrent antidepressant therapy.

About Schizophrenia

Schizophrenia is a disabling and chronic mental illness that affects about 1% of the US population and is characterized by multiple symptoms during an acute phase of the disorder that can include “positive” symptoms, such as auditory hallucinations and delusions that are most commonly paranoid. These symptoms can be accompanied by additional, harder to treat symptoms, such as social withdrawal, blunted emotional response and speech deficits, collectively referred to as “negative” symptoms, difficulty concentrating and disorganized thoughts, or cognitive impairment, depression, and insomnia.

Such residual symptoms often persist even after the acute positive symptoms subside, and contribute substantially to the social and employment disability associated with schizophrenia. Comorbid depression occurs in 23-57% of patients with schizophrenia and is associated with high relapse rates, higher suicide rates, and poor outcomes.

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-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. This compound has the potential to benefit patients suffering from a range of neuropsychiatric and neurodegenerative diseases. Lumateperone in 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 and efficacy of our product development candidates; our belief that lumateperone has the potential to provide antidepressant effects in patients suffering from a range of mood disorders, while offering the advantages of a favorable safety profile; our belief that lumateperone may provide advantages in the treatment of the broad symptoms associated with schizophrenia including depressive symptoms; 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; 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.

Contact:

Intra-Cellular Therapies, Inc.
Juan Sanchez, M.D.
Vice President, Corporate Communications and Investor Relations
646-440-9333

Burns McClellan, Inc.
Lisa Burns
agray@burnsmc.com
212-213-0006

MEDIA INQUIRIES:

Patrick Ryan, Esq.
Corporate Media Relations, W2Owcg
pryan@wcgworld.com

Source: Intra-Cellular Therapies Inc.