

Intra-Cellular Therapies Presents Data on Lumateperone, ITI-214 and ITI-333 at the 56th Annual Meeting of the American College of Neuropsychopharmacology

December 7, 2017

NEW YORK, Dec. 07, 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 four poster presentations at the 56th Annual Meeting of the American College of Neuropsychopharmacology being held in Palm Springs, CA, December 3-7, 2017.

The poster presentation (Abstract T189) titled "Favorable Clinical Safety Profile for Lumateperone (ITI-007) - Switching From Standard-Of-Care Antipsychotic Therapy in Patients With Schizophrenia," was presented on Tuesday, December 5, 2017, 5:30 pm — 7:30 pm during Poster Session II.

This poster presented additional data from the ITI-007-303 lumateperone open-label safety switching study in which 302 patients 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 for 2 weeks. 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 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. The data, taken together, are consistent with and extend data previously reported in placebo-controlled studies in patients with acute schizophrenia with lumateperone.

The poster presentation (Abstract M76) titled "Lumateperone Uniquely Enhances Glutamatergic Neurotransmission Through Activation of Both NMDA and AMPA Channels via a Dopamine D1 Receptor-Dependent Mechanism: Implications for Treatment of Mood Disorders," was presented on Monday, December 4, 2017, 5:30 pm — 7:30 pm during Poster Session I.

This poster presented data demonstrating that lumateperone, as a standalone agent, indirectly enhances glutamatergic neurotransmission through both AMPA and NMDA channels in the prefrontal cortex via lumateperone's dopamine D1 receptor activation. This finding had not previously been observed with an antipsychotic agent in the absence of antidepressant augmentation. Additionally, data were presented demonstrating that lumateperone, consistent with a rapid acting antidepressant effect, increases protein phosphorylation of key proteins in the mTOR pathway. These findings, in addition to the potent serotonin transporter inhibition previously described with lumateperone, suggest the potential for lumateperone to exhibit potent and rapid antidepressant effects in patients suffering from a range of mood disorders including co-morbid depression in schizophrenia, bipolar depression, major depressive disorder and treatment-resistant depression.

The poster presentation (Abstract T172) titled "ITI-214, a Potent and Selective PDE 1 Inhibitor: A New Approach to the Treatment of Neurodegenerative Diseases, Including Parkinson's Disease," was presented on Tuesday, December 5, 2017, 5:30 pm — 7:30 pm during Poster Session II.

This poster presented preclinical data showing the importance of ITI-214 and inhibition of PDE1 in reducing neuroinflammation and in regulating the function of microglial, the primary immune cells of the CNS. The presentation also highlights findings demonstrating that ITI-214 improves motor control in animal models of Parkinson's disease, enhances cognition and increases wakefulness without stimulating locomotor activity. These findings suggest ITI-214 may represent a therapeutic strategy for preventing or slowing neurodegeneration in patients with Parkinson's disease and other neurodegenerative or neuropsychiatric diseases in which neuroinflammation and microglia activation is a known component of the disease.

The poster presentation (Abstract W244) titled "Mechanism of Action ITI-333, a Novel Modulator of Serotonin, Dopamine, and Mu Opiate Receptors for the Treatment of Pain and Psychiatric Co-Morbidities Accompanying a Broad Spectrum of Substance Use Disorders," was presented on Wednesday, December 6, 2017, 5:30 pm — 7:30 pm during Poster Session III.

This poster presented preclinical data detailing the unique pharmacology of ITI-333, a compound possessing a three-pronged mechanism of action with high affinity at serotonin 5-HT_{2A}, dopamine D1 and mu opiate (MOP) receptors. The data support a potent partial agonist activity of ITI-333 at MOP receptors, as demonstrated in cell-based receptor assays, and expressed as analgesia in animal models for acute and inflammatory pain. ITI-333 mediates analgesia in pain models over a broad dose range, and, as anticipated for a compound acting as a partial agonist, blocks the effects of high doses of morphine in both pain and motor hyperactivity models. Further, ITI-333 exerts analgesic effects at doses that do not elicit gastrointestinal or respiratory side effects commonly associated with morphine use in animals. In contrast to morphine, ITI-333 also does not elicit signs of physical dependence after chronic administration to rats. Preclinical studies are currently ongoing. ITI-333 is designed as a potential treatment for substance-use disorders, pain and psychiatric comorbidities, including depression and anxiety.

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: 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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