Intra-Cellular Therapies Presents Results from ITI-214 Phase 1/2 Clinical Trial in Patients with Parkinson’s Disease at 2018 American Neurological Association Annual Meeting

October 17, 2018

NEW YORK, Oct. 17, 2018 (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 it will present top line results from the Company’s Phase 1/2 clinical study of ITI-214, its potent and selective phosphodiesterase 1 (PDE1) inhibitor, in patients with mild to moderate Parkinson’s disease (PD) being maintained on stable (concomitant) PD medication, at the 2018 American Neurological Association Annual Meeting being held in Atlanta, Georgia, October 21-24, 2018. This multiple ascending dose cohort study was designed to evaluate the safety and tolerability of ITI-214 and to explore the potential for ITI-214 to treat both motor and nonmotor symptoms associated with PD.

The poster presentation (M217) entitled, “A Phase I/II Clinical Study of ITI-214, a Novel Phosphodiesterase I Inhibitor, for the Treatment of Motor and Non-motor Symptoms of Parkinson’s Disease” is being presented Monday, October 22, 2018, 5:30 pm - 7:00 pm ET.

About ITI-214

ITI-214 is a potent and selective phosphodiesterase 1 (PDE1) inhibitor. As the clinical lead compound in the Company’s PDE1 portfolio, ITI-214, has been found to be generally well tolerated with a favorable safety profile in four Phase 1 clinical trials, in healthy volunteers. Inhibitors of PDE1 block the breakdown of cyclic nucleotides (cAMP, cGMP), potentiating downstream intracellular signaling. The PDE1 enzyme is highly active in pathological or disease states, and our PDE1 inhibitors are designed to reestablish normal function in these disease states. PDE1 inhibitors have minimal effect on normal function, only acting when cells in the nervous system are stimulated. These "on-demand" effects make this an exciting and novel approach for the treatment of disease. In animal models, inhibition of PDE1 has been shown to reduce neuroinflammation and to reduce neurodegeneration. The mechanism of action of PDE1 inhibitors suggests therapeutic potential across a variety of neurological and cardiovascular diseases.

Preclinical studies suggest that PDE1 inhibitors potentiate L-DOPA and other dopamine replacement therapies yielding improved motor symptom control while reducing adverse motor complications associated with these treatments. Preclinical models have also shown the potential for PDE-1 inhibitors to address non-motor symptoms such as excessive daytime sleepiness, cognitive impairment and other non-motor symptoms. The Company has recently demonstrated the importance of ITI-214 and inhibition of PDE1 in reducing neuroinflammation and in regulating microglial function suggesting utility in treating neurodegenerative and neuropsychiatric disease.

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. Ultimately, treatments are needed that protect dopamine containing neurons from damage, providing novel approaches for slowing or halting disease progression. The impact of ITI-214 may be examined in future, longer term studies.

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 clinical and nonclinical development plans for our PDE compounds, including our expectations concerning the timing of trials and studies and the availability of data; our beliefs about the potential uses and benefits of ITI-214; 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 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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