Intra-Cellular Therapies Presents Data on ITI-214 at the 2018 American Academy of Neurology Annual Meeting

April 26, 2018

Phase 1/2 clinical trial in patients with Parkinson's disease (PD) expanded to add additional cohort.

NEW YORK, April 26, 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 it is presenting a poster on ITI-214, its novel selective phosphodiesterase 1 (PDE1) inhibitor, at the 2018 American Academy of Neurology Annual Meeting being held in Los Angeles, CaliforniaApril 21-27, 2018.

The poster presentation (P5-067) entitled “ITI-214, A Novel Phosphodiesterase Type I Inhibitor, for the Treatment of Motor and Non-motor Symptoms of Parkinson's Disease” is being presented today Thursday April 26, 2018, 5:30 pm — 7:00 pm during Poster Session 5.

The presentation highlights preclinical findings showing anti-neuroinflammatory and neuroprotective effects associated with exposure to ITI-214 and provides an update regarding the ongoing Phase 1/2 clinical study in patients with PD. This study is designed to evaluate the safety and tolerability of ITI-214 in this patient population and to explore the ability of ITI-214 to treat both motor and nonmotor symptoms associated with PD. Clinical conduct has been completed for the first three cohorts (1, 3, and 10 mg). At these doses, ITI-214 was safe and generally well tolerated. Based on this favorable safety and tolerability profile, the study has been expanded to include a 30 mg dose cohort. We anticipate top-line results from this trial will be available in 2H 2018.

The poster presentation also highlights the mechanism of action of PDE1 inhibitors as well as findings demonstrating that ITI-214 improves motor control in preclinical models of PD, enhances cognition and increases wakefulness without stimulating locomotor activity.

About the ITI-214-105 Phase 1/2 Clinical Trial

This is a Phase 1/2 randomized, double-blind, placebo-controlled, multiple rising dose study of ITI-214 in patients with idiopathic PD. Patients with mild to moderate PD who are maintained on stable PD therapy will be randomly assigned to placebo or ITI-214 administered orally once daily for 7 days. The primary objective is to evaluate the safety and tolerability of ITI-214 in this patient population. Three cohorts have been completed (1, 3 and 10 mg) and the trial has been expanded to include a fourth cohort (30 mg). Secondary objectives are to evaluate the pharmacokinetic profile of ITI-214 and explore its potential utility to control motor fluctuations and to evaluate treatment of non-motor symptoms (daytime sleepiness, dysautonomia) associated with PD. Biomarkers of disease progression (inflammation) are being assessed.

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 as well as patients with schizophrenia. 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 potential 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 for motor symptom control at lower doses of dopamine replacement therapies while inhibiting the adverse dyskinesias induced by 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. In preclinical studies, 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.

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 development plans for our PDE program, including ITI-214, including the anticipated timing for the availability of data from our ongoing Phase 1/2 trial of ITI-214; 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: risks associated with our current and planned clinical trials, we may encounter unexpected

safety or tolerability issues with lumateperone or our other product candidates in ongoing or future trials and other development activities, 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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