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Intra-Cellular Therapies Announces Initiation of ITI-007-201 Phase 3 Clinical Trial for the Treatment of Agitation in Patients with Dementia, Including Alzheimer's Disease

NEW YORK, June 28, 2016 (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 that, following communication with the U.S. Food and Drug Administration (FDA), the Company has initiated Phase 3 development of ITI-007 for the treatment of agitation in patients with dementia, including Alzheimer's disease (AD).

"I am pleased to announce the advancement of ITI-007 into Phase 3 development for the treatment of behavioral disturbances associated with dementia as we continue in our mission to provide improved treatment options to patients suffering from CNS disorders," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "Agitation associated with dementia imparts considerable distress for patients and burden on their caregivers. Given ITI-007's unique pharmacology, we believe that its ability to fully occupy serotonin 5-HT2A receptors at low doses, while modestly modulating dopamine D2 and D1 receptors, and inhibit serotonin reuptake will improve a wide range of behavioral disturbances associated with dementia, including agitation. We believe the favorable safety and tolerability profile of ITI-007 observed in other patient populations will translate well into this new therapeutic area to ease suffering and improve quality of life for patients and their families."

About the ITI-007-201 Phase 3 Trial

The ‘201 trial is a Phase 3 multicenter, randomized, double-blind, placebo-controlled clinical trial in patients with a clinical diagnosis of probable AD and clinically significant symptoms of agitation. In this trial, approximately 360 patients are planned to be randomized to receive 9 mg ITI-007 or placebo in a 1:1 ratio orally once daily for four weeks.

This study includes a single interim analysis reviewed by an independent data monitoring committee, which will be used to assess the assumptions of variability and effect size.

The primary efficacy measure is the Cohen-Mansfield Agitation Inventory — Community version (CMAI-C). The CMAI-C is a well-validated 37-item scale that measures the ability of a drug to reduce overall frequency of agitation symptoms, including aggressive behaviors. Individual items are rated by an expert clinician on a scale of 1 to 7 in which a score of 7 represents the most frequent for each item assessed. The key secondary efficacy measure is a Clinical Global Impression scale for Severity (CGI-S) of illness. Other exploratory secondary endpoints include measures of other behavioral disturbances associated with dementia. Safety and tolerability are also assessed in the trial.

About Agitation Associated with Dementia

According to the Alzheimer's Association, 5.2 million people in the United States are living with Alzheimer's disease, and it is currently the fifth leading cause of death for people age 65 and older. It has been estimated that 44.4 million people worldwide were living with dementia in 2013. This number is expected to increase to 75.6 million by 2030 and to increase to 135.5 million by 2050. While the diagnostic criteria for Alzheimer's disease mostly focus on the related cognitive deficits, it is often the behavioral and psychiatric symptoms that are most troublesome for caregivers and lead to poor quality of life for patients. These symptoms include agitation (including aggression), depression, sleep disorders, and psychosis. Studies have suggested that approximately 60% of patients with Alzheimer's disease experience agitation. According to the International Psychogeriatric Association, the definition of agitation includes excessive motor activity such as pacing and restlessness, verbal aggression such as screaming and shouting, and physical aggression such as grabbing, pushing, and hitting. Such behaviors are clinically meaningful and may warrant treatment when they are persistent or frequently recurrent, are associated with emotional distress, and severe enough to interfere with interpersonal relationships, other aspects of social functioning and/or ability to perform or participate in daily living activities.

The FDA has not approved any drug to treat the behavioral symptoms of Alzheimer's disease. As symptoms progress and become more severe, physicians often resort to off-label use of antipsychotic medications in these patients. Current antipsychotic drugs are associated with a number of side effects, which can be problematic for elderly patients with Alzheimer's disease. In addition, antipsychotic drugs may exacerbate the cognitive disturbances associated with Alzheimer's disease. There is a large unmet medical need for a safe and effective therapy to treat the behavioral symptoms in patients with Alzheimer's disease.

About ITI-007

ITI-007 is our lead drug development candidate with mechanisms of action that, we believe, have the potential to yield a first-in-class therapy for multiple therapeutic indications. In our pre-clinical and clinical trials to date, ITI-007 combines potent serotonin 5-HT2A receptor antagonism, dopamine receptor phosphoprotein modulation (DPPM), glutamatergic modulation, and serotonin reuptake inhibition into a single drug candidate for the treatment of acute and residual schizophrenia, as well as for the treatment of bipolar disorder, including bipolar depression. At dopamine D2 receptors, ITI-007 has been demonstrated to have dual properties and to act as both a post-synaptic antagonist and a pre-synaptic partial agonist. ITI-007 has also been demonstrated to stimulate phosphorylation of glutamatergic NMDA GluN2B receptors in a mesolimbic specific manner. We believe that this regional selectivity in brain areas thought to mediate the efficacy of antipsychotic drugs, together with serotonergic, glutamatergic, and dopaminergic interactions, may result in efficacy for a broad array of symptoms associated with schizophrenia and bipolar disorder with improved psychosocial function. The serotonin reuptake inhibition potentially allows for antidepressant activity in the treatment of schizoaffective disorder, co-morbid depression, and/or as a stand-alone treatment for major depressive disorder. We believe ITI-007 may also be useful for the treatment of other psychiatric and neurodegenerative disorders, particularly behavioral disturbances associated with dementia, autism, and other CNS diseases.

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, ITI-007, for the treatment of schizophrenia, bipolar disorder, behavioral disturbances in dementia, depression and other neuropsychiatric and neurological disorders. ITI-007, a first-in-class molecule, is in Phase 3 clinical development for the treatment of schizophrenia, bipolar depression, and agitation associated with dementia. The Company is also utilizing its phosphodiesterase platform and other proprietary chemistry platforms to develop drugs for the treatment of CNS and other disorders.

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 non-clinical development plans; the progress, timing and results of our clinical trials; the safety and efficacy of our product development candidates; our beliefs about the potential uses and benefits of ITI-007; our beliefs about unmet medical needs; and our research 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 ITI-007, 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 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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