Intra-Cellular Therapies Announces Investor Webcast and Presentations on Lumateperone Programs at the Upcoming American Psychiatric Association (APA) Annual Meeting

April 22, 2021

Webcast to be Held Tuesday, May 4, 2021 at 2:00 p.m. EDT

Webcast Will Feature Key Opinion Leader, Dr. Roger McIntyre, Professor of Psychiatry and Pharmacology at the University of Toronto and Head of the Mood Disorders Psychopharmacology Unit at the University Health Network, Toronto, Canada

NEW YORK, April 22, 2021 (GLOBE NEWSWIRE) -- Intra-Cellular Therapies, Inc. (Nasdaq: ITCI), a biopharmaceutical company focused on the development and commercialization of therapeutics for central nervous system (CNS) disorders, announces lumateperone presentations at the upcoming American Psychiatric Association (APA) Annual Meeting to be held May 1-3, 2021 and will hold a webcast on May 4, 2021.

Dr. McIntyre will describe the lumateperone data presented at APA in the context of existing medical needs in the treatment mood disorders including bipolar disorder, and “mixed features” in bipolar disorder and major depressive disorder.

The presentations at APA highlight lumateperone clinical data in bipolar depression including in patients who exhibit mixed features and patients with schizophrenia with co-morbid depression as well as detailing lumateperone’s favorable safety and tolerability profile.

The titles and presenters of the poster presentations are as follows:

Sunday, May 2, 2021, 3:30 p.m.-4:00 p.m. EDT

- “The Safety and Tolerability of Lumateperone 42 mg for the Treatment of Bipolar Depression: A Pooled Analysis of 2 Randomized Placebo-Controlled Trials” (P8-106), presented by Susan L. McElroy, MD.

Monday, May 3, 2021, 1:30 p.m.-2:00 p.m. EDT

- “Adjunctive Lumateperone (ITI-007) in the Treatment of Bipolar Depression: Results from a Randomized Clinical Trial” (P11-023), presented by Lakshmi N. Yatham, MBBS, FRCPC, MRCPsych, MBA.
- “The Efficacy of Lumateperone in Patients with Bipolar Depression With and Without Mixed Symptoms” (P11-036), presented by Roger S. McIntyre, MD.
- “Efficacy of Lumateperone (ITI-007) in Depression Symptoms Associated With Schizophrenia” (P11-087), presented by Robert E. Davis, PhD.

Investor webcast on, May 4, 2021

The Company will host a webcast on May 4, 2021 at 2:00 p.m. EDT. The webcast will feature Dr. Roger McIntyre, Professor of Psychiatry and Pharmacology at the University of Toronto and Head of the Mood Disorders Psychopharmacology Unit at the University Health Network, Toronto, Canada.

The live webcast and subsequent replay may be accessed by visiting the Company's website at www.intracellulartherapies.com. Please connect to the Company's website at least 5-10 minutes prior to the live webcast to ensure adequate time for any necessary software download.

About Bipolar Depression

Bipolar I and Bipolar II disorder are serious, highly prevalent psychiatric conditions affecting approximately 11 million adults in the U.S.

These disorders are characterized by recurrent episodes of mania or hypomania interspersed with episodes of major depression known as Bipolar depression. Bipolar I and Bipolar II each represent about half of the overall population of patients with bipolar disorder.

Bipolar depression is the most common clinical presentation of bipolar disorder. These episodes tend to last longer, recur more often, and are associated with a worse prognosis than the manic/hypomanic episodes. Bipolar depression remains a significantly underserved medical need, with only a few FDA-approved treatment options available. These treatments are commonly associated with tolerability issues.

CAPLYTA® (lumateperone) is under investigation for the treatment of bipolar disorder. The safety and efficacy for this use has not been established.

CAPLYTA is indicated for the treatment of schizophrenia in adults. CAPLYTA is available in 42 mg capsules.

Important Safety Information

Boxed Warning: Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.

CAPLYTA is not approved for the treatment of patients with dementia-related psychosis.

Contraindications: CAPLYTA is contraindicated in patients with known hypersensitivity to lumateperone or any components of CAPLYTA.

Warnings & Precautions: Antipsychotic drugs have been reported to cause:

- **Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis**, including stroke and transient ischemic attack. See BOXED WARNING above.
- **Neuroleptic Malignant Syndrome**, which is a potentially fatal reaction. Signs and symptoms include: hyperpyrexia, muscle rigidity, delirium, autonomic instability, elevated creatinine phosphokinase, myoglobinuria (and/or rhabdomyolysis), and acute renal failure. Manage with immediate discontinuation of CAPLYTA and close monitoring.
- **Tardive Dyskinesia**, a syndrome of potentially irreversible, dyskinetic, and involuntary movements which may increase as the duration of treatment and total cumulative dose increases. Discontinue CAPLYTA if clinically appropriate.
- **Metabolic Changes**, including hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. Measure weight and assess fasting plasma glucose and lipids when initiating CAPLYTA and monitor periodically during long-term treatment.
- **Leukopenia, Neutropenia, and Agranulocytosis (including fatal cases)**. Perform complete blood counts in patients with pre-existing low white blood cell count (WBC) or history of leukopenia or neutropenia. Discontinue CAPLYTA if clinically significant decline in WBC occurs in absence of other causative factors.
- **Orthostatic Hypotension and Syncope**. Monitor heart rate and blood pressure and warn patients with known cardiovascular or cerebrovascular disease.
- **Falls**. CAPLYTA may cause somnolence, postural hypotension, and motor and/or sensory instability, which may lead to falls and, consequently, fractures and other injuries. Assess patients for risk when using CAPLYTA.
- **Seizures**. Use CAPLYTA cautiously in patients with a history of seizures or with conditions that lower seizure threshold.
- **Potential for Cognitive and Motor Impairment**. Advise patients to use caution when operating machinery or motor vehicles until they are reasonably certain CAPLYTA therapy does not affect them adversely.
- **Body Temperature Dysregulation**. Use CAPLYTA with caution in patients who may experience conditions that may increase core body temperature such as strenuous exercise, extreme heat, dehydration, or concomitant anticholinergics.
- **Dysphagia**. Use CAPLYTA with caution in patients at risk for aspiration.

Drug Interactions: Avoid concomitant use with CYP3A4 inducers and moderate or strong CYP3A4 inhibitors.

Special Populations: Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. Breastfeeding is not recommended. Avoid use in patients with moderate or severe hepatic impairment.

Adverse Reactions: The most common adverse reactions in clinical trials with CAPLYTA vs. placebo were somnolence/sedation (24% vs. 10%) and dry mouth (6% vs. 2%).

Please click here to see full Prescribing Information including **Boxed Warning.**

About CAPLYTA (lumateperone)

CAPLYTA is an oral, once daily medicine approved for the treatment of schizophrenia of adults (42mg/day).

The mechanism of action of CAPLYTA in the treatment of schizophrenia is unknown. However, the efficacy of CAPLYTA could be mediated through a combination of antagonist activity at central serotonin 5-HT2A receptors and postsynaptic antagonist activity at central dopamine D2 receptors.

CAPLYTA is being developed for the treatment of bipolar depression, behavioral disturbances in patients with dementia, including Alzheimer's disease, depression and other neuropsychiatric and neurological disorders. CAPLYTA has not been demonstrated to be safe and effective in these other areas.

About Intra-Cellular Therapies

Intra-Cellular Therapies is a biopharmaceutical company founded on Nobel prize-winning research that allows us to understand how therapies affect the inner-workings of cells in the body. The company leverages this intracellular approach to develop innovative treatments for people living with complex psychiatric and neurologic diseases.

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 or other studies for 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; the COVID-19 pandemic may negatively impact the conduct of, and the timing of enrollment, completion and reporting with respect to, our clinical trials; any other impacts on our business as a result of or related to the COVID-19 pandemic; 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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