CAPLYTA® (lumateperone) Open-Label Safety Switching Study in Patients with Schizophrenia Published in the Journal, Schizophrenia Research

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Patients with stable symptoms of schizophrenia were switched from previous antipsychotic medications with no dose titration to CAPLYTA 42 mg for a 6-week treatment duration, then switched back to previous or another approved antipsychotic.

In patients with stable symptoms of schizophrenia, CAPLYTA was well-tolerated with low rates of metabolic and extrapyramidal symptoms (EPS) adverse events; schizophrenia symptoms remained stable and did not worsen from baseline.

NEW YORK, Jan. 21, 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, today announced the publication of results from the CAPLYTA clinical trial (ITI-007-303) in adult patients with schizophrenia. The article, "Safety and tolerability of lumateperone 42 mg: An open-label antipsychotic switch study in outpatients with stable schizophrenia" (Correll et al. 2021), was recently published online in Schizophrenia Research and is available here.

The objective of this 6-week open-label study was to evaluate the safety and tolerability of CAPLYTA with stable schizophrenia patients switched from another antipsychotic treatment. The most common drug-related treatment emergent adverse events during CAPLYTA treatment were somnolence (6.6%), headache (5.3%) and dry mouth (5.3%). Reports of EPS were low (1%).

After 6 weeks of CAPLYTA treatment, it was observed that the mean total cholesterol, low-density lipoprotein (LDL) cholesterol, body weight and prolactin levels decreased from baseline. At the conclusion of the treatment period with CAPLYTA, patients were switched back to their previous or another approved antipsychotic. In a prespecified secondary safety analysis, conducted 2 weeks after discontinuing CAPLYTA, it was observed that the mean total cholesterol, LDL cholesterol, body weight and prolactin levels increased. In this study, patients' schizophrenia symptoms remained stable and did not worsen from baseline.

These data further support the safety, tolerability and effectiveness of CAPLYTA in patients with schizophrenia and provide important information to clinicians.

"Weight gain and metabolic side effects or motor disturbances are leading reasons for healthcare providers to switch antipsychotics. Scientific results from studies that resemble a real world clinical setting and published in the medical literature provide important information for clinicians to make informed treatment decisions," said Dr. Christoph Correll, Professor of Psychiatry and Molecular Medicine at the Zucker School of Medicine at Hofstra/Northwell, New York. "CAPLYTA is a valuable addition to the armamentarium to help treat this challenging mental illness."

About ITI-007-303

ITI-007-303 is an open label, multicenter study conducted in the United States to investigate the safety and effectiveness of up to 1 year of treatment with CAPLYTA 42 mg in 301 stable patients with schizophrenia after switching from previous antipsychotic medications with no dose titration to CAPLYTA 42 mg. The study was conducted in 2 parts.

In Part 1, patients were eligible for participation if they had stable psychopathology and were able to be treated on an outpatient basis after Day 5. Entering the screening period on an existing antipsychotic was not a requirement of the study; therefore, medication history could not always be verified.

Patients meeting entry criteria were required to discontinue previous antipsychotics, tapering as appropriate, prior to starting CAPLYTA 42 mg with no dose titration. The primary objective assessed adverse events (AE), vital signs, laboratory tests, and extrapyramidal symptoms (EPS). Three hundred and one patients received CAPLYTA in the study and the 6-week treatment was completed by 218 (72.2%) of patients. The most common reason for treatment discontinuation was adverse events (8.9%). At the conclusion of the treatment period with CAPLYTA, patients were switched to their previous or another approved antipsychotic and a follow-up safety assessment was conducted approximately 2 weeks later.

In Part 2 of this study, patients were treated for up to 1 year and the favorable safety profile was maintained. Data from Part 2 of the study will be published in a separate report.

CAPLYTA® (lumateperone) 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. Reactions have included pruritus, rash (e.g. allergic dermatitis, papular rash, and generalized rash), and urticaria.
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 (NMS)**, which is a potentially fatal reaction. Signs and symptoms include: high fever, stiff muscles, confusion, changes in breathing, heart rate, and blood pressure, elevated creatinine phosphokinase, myoglobinuria (and/or rhabdomyolysis), and acute renal failure. Patients who experience signs and symptoms of NMS should immediately contact their doctor or go to the emergency room.
- **Tardive Dyskinesia**, a syndrome of uncontrolled body movements in the face, tongue, or other body parts, which may increase with duration of treatment and total cumulative dose. TD may not go away, even if CAPLYTA is discontinued. It can also occur after CAPLYTA is discontinued.
- **Metabolic Changes**, including hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. Hyperglycemia, in some cases extreme and associated with ketoacidosis, hyperosmolar coma or death, has been reported in patients treated with antipsychotics. 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)**. Complete blood counts should be performed in patients with pre-existing low white blood cell count (WBC) or history of leukopenia or neutropenia. CAPLYTA should be discontinued if clinically significant decline in WBC occurs in absence of other causative factors.
- **Decreased Blood Pressure & Dizziness**. Patients may feel lightheaded, dizzy or faint when they rise too quickly from a sitting or lying position (orthostatic hypotension). Heart rate and blood pressure should be monitored and patients should be warned with known cardiovascular or cerebrovascular disease. Orthostatic vital signs should be monitored in patients who are vulnerable to hypotension.
- **Falls**. CAPLYTA may cause sleepiness or dizziness and can slow thinking and motor skills, which may lead to falls and, consequently, fractures and other injuries. Patients should be assessed for risk when using CAPLYTA.
- **Seizures**. CAPLYTA should be used cautiously in patients with a history of seizures or with conditions that lower seizure threshold.
- **Sleepiness and Trouble Concentrating**. Patients should use caution when operating machinery or motor vehicles until they know how CAPLYTA affects them.
- **Body Temperature Dysregulation**. CAPLYTA should be used 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**. CAPLYTA should be used with caution in patients at risk for aspiration.

Drug Interactions: CAPLYTA should not be used with CYP3A4 inducers, moderate or strong CYP3A4 inhibitors and UGT inhibitors.

Special Populations: Newborn infants 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. Use of CAPLYTA should be avoided in patients with moderate or severe liver problems.

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 42mg/day is an oral, once daily atypical antipsychotic approved for the treatment of schizophrenia of adults. While the mechanism of action of CAPLYTA in the treatment of schizophrenia is unknown, 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.

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. For more information, please visit www.intracellulartherapies.com.

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, whether clinical trial results will be predictive of future real-world results; our beliefs about the potential utility of our 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: there are no guarantees that CAPLYTA will be commercially successful; we may encounter issues, delays or other challenges in commercializing CAPLYTA; the COVID-19 pandemic may negatively impact our commercial plans and sales for CAPLYTA; the COVID-19 pandemic may negatively impact the conduct of, and the timing of enrollment, completion and reporting with respect to, our clinical trials; whether CAPLYTA receives adequate reimbursement from third-party payors; the degree to which CAPLYTA receives acceptance from patients and physicians for its approved indication; challenges associated with execution of our sales activities, which in each case could limit the potential of our product; results achieved in CAPLYTA in the treatment of

schizophrenia following commercial launch of the product may be different than observed in clinical trials, and may vary among patients; any other impacts on our business as a result of or related to the COVID-19 pandemic; risks associated with our current and planned clinical trials; we may encounter unexpected safety or tolerability issues with CAPLYTA following commercial launch for the treatment of schizophrenia or in ongoing or future trials and other development activities; 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 or in clinical trials for other indications; 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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