Johnson&Johnson

NEWS RELEASE

Johnson & Johnson Closes Landmark Intra-Cellular Therapies, Inc. Acquisition to Solidify Neuroscience Leadership

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Advances Company's industry-leading portfolio in mental health with addition of CAPLYTA® (lumateperone), the first and only U.S. FDA-approved treatment for bipolar I and II depression as an adjunctive therapy and monotherapy; also approved for the treatment of schizophrenia in adults

sNDA submitted to U.S. FDA for CAPLYTA® as adjunctive treatment for major depressive disorder; if approved, has potential to become a new standard of care for most common depressive disorders

Addition of CAPLYTA® strengthens J&J's robust lineup of therapies with $5 billion+ potential in peak year sales[i], further solidifying sales growth above analyst expectations now through the remainder of the decade

Acquisition also includes promising clinical-stage pipeline with best-in-class potential in generalized anxiety disorder and Alzheimer's disease-related psychosis and agitation

NEW BRUNSWICK, N.J.--(BUSINESS WIRE)-- Johnson & Johnson (NYSE: JNJ) today announced it has completed its acquisition of Intra-Cellular Therapies, Inc. Intra-Cellular Therapies is now part of Johnson & Johnson and will operate as a business unit within Johnson & Johnson Innovative Medicine.

"At Johnson & Johnson, we are committed to transforming care for the millions of people worldwide living with neuropsychiatric and neurodegenerative disorders," said Joaquin Duato, Chairman and Chief Executive Officer, Johnson & Johnson. "We are excited to officially welcome the talented Intra-Cellular Therapies team to the Company, and we look forward to working together as we realize our ambition of becoming the number one

neuroscience company worldwide."

With this acquisition, Johnson & Johnson adds CAPLYTA® (lumateperone) to its robust portfolio of differentiated medicines. CAPLYTA® is a once-daily oral therapy approved to treat adults with schizophrenia, as well as the first and only U.S. Food and Drug Administration (FDA)-approved treatment for depressive episodes associated with bipolar I or II disorder (bipolar depression), as a monotherapy and adjunctive therapy with lithium or valproate. In February 2025, Intra-Cellular Therapies announced that the U.S. FDA accepted its supplemental new drug application for CAPLYTA® as an adjunctive treatment for adults with major depressive disorder (MDD). The acquisition also includes ITI-1284, a promising Phase 2 compound being studied in generalized anxiety disorder (GAD) and Alzheimer's disease-related psychosis and agitation, as well as a clinical-stage pipeline that further complements Johnson & Johnson's current areas of focus.

"We are focused on investing in what we believe is the future of innovation across our targeted therapeutic areas, including neuroscience," said Jennifer Taubert, Executive Vice President, Worldwide Chairman, Innovative Medicine, Johnson & Johnson. "We are pleased to finalize this acquisition, which serves as a strategic near- and long-term growth catalyst for Johnson & Johnson, and we look forward to working together to continue transforming treatment and patient care for some of today's most debilitating neuropsychiatric and neurodegenerative disorders."

The transaction is expected to accelerate 2025 sales growth for Johnson & Johnson by approximately 0.8% with approximately $0.7 billion in incremental sales. Inclusive of the impact of financing costs, Johnson & Johnson expects the transaction to dilute adjusted earnings per share (EPS) by approximately $0.25 in 2025, an improvement from the $0.30 – $0.35 originally estimated on the Company's Q4 2024 earnings call. In 2026, Johnson & Johnson expects the earnings dilution to be reduced to approximately $0.21 per share as annualized financing costs are partially offset by operational accretion. Johnson & Johnson will include these estimates in its full-year 2025 financial outlook when it reports first quarter results on April 15, 2025.

In connection with the completion of the transaction, Intra-Cellular Therapies' common stock ceased trading on the NASDAQ Global Select Market.

Indication

CAPLYTA® (lumateperone) is indicated in adults for the treatment of schizophrenia and for the treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate.

Important Safety Information

Boxed Warnings:

- 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.
- Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adults in short-term studies. All antidepressant-treated patients should be closely monitored for clinical worsening and for emergence of suicidal thoughts and behaviors. The safety and effectiveness of CAPLYTA® have not been established in pediatric patients.

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 (TD), 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.
- Potential for Cognitive and Motor Impairment. 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. Dose reduction is recommended for concomitant use with strong CYP3A4 inhibitors or moderate CYP3A4 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. Dose reduction is recommended for patients with moderate or severe hepatic impairment.

Adverse Reactions: The most common adverse reactions in clinical trials with CAPLYTA® vs. placebo were somnolence/sedation, dizziness, nausea, and dry mouth.

CAPLYTA® is available in 10.5 mg, 21 mg, and 42 mg capsules.

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

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more at **www.jnj.com/** or at **www.innovativemedicine.jnj.com**. Follow us at **@JNJInnovMed**.

CAUTIONS CONCERNING FORWARD-LOOKING STATEMENTS:

- This press release contains “forward-looking statements” regarding the acquisition of Intra-Cellular Therapies

by Johnson & Johnson and CAPLYTA®and development programs. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Johnson & Johnson or Intra-Cellular Therapies.

- Risks and uncertainties include, but are not limited to: challenges inherent in product research and development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success for new products; manufacturing difficulties and delays; product efficacy or safety concerns resulting in product recalls or regulatory action; economic conditions, including currency exchange and interest rate fluctuations; the risks associated with global operations; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes to applicable laws and regulations, including tax laws and global health care reforms; adverse litigation or government action; changes in behavior and spending patterns or financial distress of purchasers of health care services and products; and trends toward health care cost containment.
- In addition, there will be risks and uncertainties related to the ability of the Johnson & Johnson family of companies to successfully integrate the programs, products, technologies and employees/operations and clinical work of Intra-Cellular Therapies. A further list and description of these risks, uncertainties and other factors and the general risks associated with the respective businesses of Johnson & Johnson and Intra-Cellular Therapies can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2024, filed with the SEC on February 13, 2025, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent filings with the SEC and in Intra-Cellular Therapies' Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the SEC on February 21, 2025, including in the sections captioned "Cautionary Statement Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Intra-Cellular Therapies' subsequent filings with the SEC. Copies of these filings, as well as subsequent filings, are available online at**www.sec.gov**,**www.jnj.com**,**www.intracellulartherapies.com**, or on request from Johnson & Johnson or Intra-Cellular Therapies.
- Neither Johnson & Johnson nor Intra-Cellular Therapies undertakes to update any forward-looking statement as a result of new information or future events or developments, except as required by law.

[i] Non risk adjusted peak year sales including partner sales

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