Johnson&Johnson

NEWS RELEASE

Johnson & Johnson Strengthens Neuroscience Leadership with Acquisition of Intra-Cellular Therapies, Inc.

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Acquisition includes CAPLYTA® (lumateperone), the first and only U.S. FDA-approved treatment for bipolar I and II depression as an adjunctive 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, CAPLYTA® has potential to become a standard of care for most common depressive disorders

CAPLYTA® adds to Johnson & Johnson's robust lineup of therapies with $5 billion+ potential in peak year sales [i] and further solidifies sales growth above analyst expectations now through the remainder of the decade

Promising clinical-stage pipeline with best-in-disease potential in generalized anxiety disorder and Alzheimer's disease-related psychosis and agitation

NEW BRUNSWICK, N.J. & BEDMINSTER, N.J.--(BUSINESS WIRE)-- Johnson & Johnson (NYSE: JNJ) and Intra-Cellular Therapies, Inc. (Nasdaq: ITCI) announced today that they have entered into a definitive agreement under which Johnson & Johnson will acquire all outstanding shares of Intra-Cellular Therapies, a biopharmaceutical company focused on the development and commercialization of therapeutics for central nervous system (CNS) disorders, for $132.00 per share in cash for a total equity value of approximately $14.6 billion.

"Building on our nearly 70-year legacy in neuroscience, this unique opportunity to add Intra-Cellular Therapies to our Innovative Medicine business demonstrates our commitment to transforming care and advancing research in some of today's most devastating neuropsychiatric and neurodegenerative disorders," said Joaquin Duato,

Chairman and Chief Executive Officer, Johnson & Johnson. “This acquisition further differentiates our portfolio, serves as a strategic near- and long-term growth catalyst for Johnson & Johnson and offers compelling value to patients, health systems and shareholders.”

With this agreement, Johnson & Johnson adds Intra-Cellular Therapies’ CAPLYTA® (lumateperone), a once-daily oral therapy approved to treat adults with schizophrenia, as well as depressive episodes associated with bipolar I or II disorder (bipolar depression), as a monotherapy and adjunctive therapy with lithium or valproate. 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 and strengthens Johnson & Johnson’s current areas of focus.

“We are excited to welcome Intra-Cellular Therapies’ talented people and world-class expertise to Johnson & Johnson,” said Jennifer Taubert, Executive Vice President, Worldwide Chairman, Innovative Medicine, Johnson & Johnson. “Together, we have an opportunity to impact even more patients living with neuropsychiatric and neurodegenerative disorders, significantly advancing care and helping improve the lives of millions worldwide.”

“CAPLYTA® ’s success and the robust pipeline we have built demonstrates the passion and dedication of our talented team, and we are proud of the hundreds of thousands of patients we have helped,” said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. “Johnson & Johnson has a longstanding commitment to neuroscience, and we believe together, we can reach even more patients around the world.”

In December 2024, Intra-Cellular Therapies announced the submission of a supplemental new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) for CAPLYTA® as an adjunctive treatment for adults with major depressive disorder (MDD). In two global, double-blind, placebo-controlled Phase 3 studies, CAPLYTA® , as an adjunctive treatment to antidepressants, demonstrated a statistically significant and clinically meaningful improvement in depressive symptoms, as measured by both clinician-rated and patient-reported outcomes. The safety profile of CAPLYTA® in both studies was consistent with the existing body of clinical data for CAPLYTA® , and no new safety concerns were identified. If approved, CAPLYTA® has the potential to be the first treatment approved for MDD and depressive symptoms associated with bipolar I and II in more than 15 years. Additional Phase 3 trials are underway with CAPLYTA® in bipolar I disorder with manic episodes or manic episodes with mixed features (bipolar mania). Positive topline results evaluating the efficacy and safety of CAPLYTA® for the prevention of relapse in adult patients with schizophrenia were shared in November 2024.

While its exact mechanism of action is unknown, CAPLYTA® is uniquely characterized by high serotonin 5-HT $_{2A}$ receptor occupancy and lower amounts of dopamine D $_{2}$ receptor occupancy at therapeutic doses. In short-term clinical studies across all three approved indications, CAPLYTA® was similar to placebo in weight change, metabolic effects, and extrapyramidal symptoms, which are often cited as reasons for treatment discontinuation. The most

common reported adverse events were somnolence/sedation, dizziness, nausea, and dry mouth. Across all three approved indications, CAPLYTA® can be taken at any time of day with or without food and does not require titration, allowing adult patients to start treatment at the effective dose.

"CAPLYTA® has robust efficacy, proven safety and favorable tolerability across all three approved indications, without the need for dose titration frequently associated with this class of therapies," said John Reed, M.D., Ph.D., Executive Vice President, R&D, Innovative Medicine, Johnson & Johnson. "With positive Phase 3 data in MDD as an adjunctive therapy and additional Phase 3 trials in other mental health disorders underway, we believe CAPLYTA® has the potential to become a new standard of care for the treatment of some of today's most prevalent and debilitating mental health disorders."

As the mental health crisis surges and the global population ages, more than one billion people worldwide – or 1 in every 8 people – are living with a neuropsychiatric or neurodegenerative disorder. In the United States:

- About 2.4 million adults live with schizophrenia, a serious, chronic mental illness that causes distortions in thinking, perceptions, emotions, and behavior;[ii,iii,iv]
- Approximately 6.1 million adults live with bipolar disorder, a chronic, lifelong illness that causes dramatic shifts in a person's mood, energy, and ability to think clearly, making it difficult for patients to carry out daily activities;[v,vi]
- An estimated 21 million adults live with MDD, one of the most common psychiatric disorders and a leading cause of disability;[vii]
- About 6.8 million adults live with GAD, a mental and behavioral disorder that causes excessive and uncontrollable worry and fear;[v] and,
- Approximately 6 million adults live with Alzheimer's disease, a neurodegenerative brain disorder that causes progressive memory loss and a decline in cognitive abilities severe enough to significantly interfere with daily life.[viii]

Transaction Details and Path to Completion

Under the terms of the agreement, Johnson & Johnson will acquire all outstanding shares of Intra-Cellular Therapies for a payment of $132.00 per share in cash. Johnson & Johnson expects to fund the transaction through a combination of cash on hand and debt. Johnson & Johnson expects to maintain a strong balance sheet and to continue to support its stated capital allocation priorities of R&D investment, competitive dividends, value-creating acquisitions, and strategic share repurchases.

The closing of the transaction is expected to occur later this year subject to applicable regulatory approvals, approval by Intra-Cellular Therapies' stockholders and other customary closing conditions for a transaction of this

type. Following completion of the transaction, Intra-Cellular Therapies' common stock will no longer be listed for trading on the Nasdaq Global Select Market.

Johnson & Johnson will provide commentary on any potential impact to Adjusted Earnings Per Share (EPS) from the transaction when it provides its initial full year 2025 guidance during the fourth quarter earnings call on Wednesday, January 22, 2025.

Advisors

Citi is serving as financial advisor to Johnson & Johnson, and Cravath, Swaine & Moore is serving as legal advisor. Centerview Partners LLC and Jefferies are serving as financial advisors to Intra-Cellular Therapies, and Davis Polk & Wardwell LLP is serving as legal advisor.

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 , 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/**.

About Intra-Cellular Therapies, Inc.

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**.

ADDITIONAL INFORMATION AND WHERE TO FIND IT

This press release may be deemed to be solicitation material in respect of the proposed acquisition of Intra-Cellular Therapies by Johnson & Johnson. In connection with the proposed transaction, Intra-Cellular Therapies intends to file relevant materials with the U.S. Securities and Exchange Commission (“SEC”), including Intra-Cellular Therapies’ proxy statement in preliminary and definitive form. INVESTORS AND STOCKHOLDERS OF INTRA-CELLULAR THERAPIES ARE URGED TO READ ALL RELEVANT DOCUMENTS FILED WITH THE SEC, INCLUDING INTRA-CELLULAR THERAPIES’ PROXY STATEMENT (WHEN THEY ARE AVAILABLE), BECAUSE THEY CONTAIN OR WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND THE PARTIES TO THE PROPOSED TRANSACTION. Investors and stockholders of Intra-Cellular Therapies are or will be able to obtain these materials (when they are available) free of charge at the SEC’s website at **www.sec.gov**, or free of charge from Intra-Cellular Therapies’ website at **www.intracellulartherapies.com**.

PARTICIPANTS IN THE SOLICITATION

Johnson & Johnson and Intra-Cellular Therapies and certain of their respective directors and executive officers, under SEC rules, may be deemed to be "participants" in the solicitation of proxies from stockholders of Intra-Cellular Therapies in connection with the proposed transaction. Information about Johnson & Johnson's directors and executive officers is available in Johnson & Johnson's Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the SEC on February 16, 2024, and Johnson & Johnson's definitive proxy statement for its 2024 annual meeting of stockholders, which was filed with the SEC on March 13, 2024. Information about Intra-Cellular Therapies' directors and executive officers is available in Intra-Cellular Therapies' Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the SEC on February 22, 2024, and Intra-Cellular Therapies' definitive proxy statement for its 2024 annual meeting of stockholders, which was filed with the SEC on April 29, 2024. To the extent holdings of Johnson & Johnson's or Intra-Cellular Therapies' securities by their respective directors or executive officers have changed since the amounts set forth in such 2024 proxy statements, such changes have been or will be reflected on Initial Statements of Beneficial Ownership on Form 3 or Statements of Change in Ownership on Form 4 filed with the SEC, including the Form 3 filed by Sanjeev Narula on **August 14, 2024** and the Form 4s filed by: Sharon Mates on **August 23, 2024**, **August 28, 2024**, **August 30, 2024** and **December 6, 2024** ; Joel S. Marcus on **June 18, 2024** and **June 25, 2024** ; Rory B. Riggs on **June 18, 2024**, **June 25, 2024**, **July 2, 2024**, **October 2, 2024**, **October 15, 2024** and **January 3, 2025** ; Eduardo Rene Salas on **June 18, 2024** and **June 25, 2024** ; Robert L. Van Nostrand on **June 18, 2024**, **June 21, 2024**, **June 25, 2024** and **July 2, 2024** ; Michael Halstead on **November 14, 2024** ; Mark Neumann on **August 20, 2024** ; and Sanjeev Narula on **August 14, 2024**. Investors and stockholders of Intra-Cellular Therapies are or will be able to obtain these documents free of charge from the SEC's website at **www.sec.gov,** from Johnson & Johnson on Johnson & Johnson's website at **www.jnj.com**, from Intra-Cellular Therapies on Intra-Cellular Therapies' website at **www.intracellulartherapies.com** or on request from Johnson & Johnson or Intra-Cellular Therapies. Additional information concerning the interests of Intra-Cellular Therapies' participants in the solicitation, which may, in some cases, be different than those of Intra-Cellular Therapies' stockholders generally, will be set forth in Intra-Cellular Therapies' proxy statement relating to the proposed transaction when it becomes available.

CAUTIONS CONCERNING FORWARD-LOOKING STATEMENTS:

- This press release contains "forward-looking statements" regarding the acquisition of Intra-Cellular Therapies by Johnson & Johnson and Intra-Cellular Therapies' product 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: the risk that the closing conditions for the acquisition will not be satisfied, including the risk that clearance under the Hart-Scott-Rodino Antitrust Improvements Act will not be obtained; uncertainty as to the percentage of Intra-Cellular Therapies stockholders that will vote to approve the proposed transaction at the Intra-Cellular Therapies stockholder meeting; the possibility that the transaction will not be completed in the expected timeframe or at all; potential adverse effects to the businesses of Johnson & Johnson or Intra-Cellular Therapies during the pendency of the transaction, such as employee departures or distraction of management from business operations; the risk of stockholder litigation relating to the transaction, including resulting expense or delay; the potential that the expected benefits and opportunities of the acquisition, if completed, may not be realized or may take longer to realize than expected; 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 31, 2023, filed with the SEC on February 16, 2024, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's most recently filed Quarterly Report on Form 10-Q and 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, 2023, filed with the SEC on February 22, 2024, including in the sections captioned "Cautionary Statement Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Intra-Cellular Therapies' most recently filed Quarterly Report on Form 10-Q and 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.

Footnotes

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

[ii] World Health Organization. Schizophrenia. Accessed December 2024. **https://www.who.int/news-room/fact-sheets/detail/schizophrenia**

[iii] Regier DA, Farmer ME, Rae DS, et al. One–month prevalence of mental disorders in the United States and sociodemographic characteristics: the epidemiologic catchment area study. Acta Psychiatr Scand. (1993);88(1):35-47. doi:10.1111/j.1600-0447.1993.tb03411.

[iv] US Census Bureau. 2010 US Census. Accessed December 23, 2024. **https://www.census.gov/topics/population/data.html**

[v] Harvard Medical School, 2007. National Comorbidity Survey (NSC). (2017, August 21). Retrieved from **https://www.hcp.med.harvard.edu/ncs/index.php**. Data Table 2: 12-month prevalence DSM-IV/WMH-CIDI disorders by sex and cohort.

[vi] Mayo Clinic. Bipolar disorder. Mayo Clinic. **https://www.mayoclinic.org/diseases-conditions/bipolar-disorder/symptoms-causes/syc-20355955**. Published August 14, 2024. Accessed December 23, 2024.

[vii] Substance Abuse and Mental Health Services Administration. Key Substance Use and Mental Health Indicators in the United States: Results from the 2021 National Survey on Drug Use and Health. Published December 2022. Accessed December 23, 2024. **https://www.samhsa.gov/data/sites/default/files/reports/rpt39443/2021NSDUHFFRRev010323.pdf**

[viii] 2024 Alzheimer's disease facts and figures. Alzheimer’s Dement. 2024;20(5):3708-3821. doi:10.1002/alz.13809.

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