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For Immediate Release

New clinical data highlights CAPLYTA® (lumateperone) as a promising option for achieving remission in adults with major depressive disorder

CAPLYTA® nearly doubled the likelihood of remission at six weeks compared to placebo as an adjunctive therapy to an antidepressant based on pooled data from two Phase 3 studies

65% of patients reached remission with CAPLYTA®, with 43% achieving sustained relief from symptoms, in a six-month open-label extension safety study

Newly approved as an adjunctive for major depressive disorder, CAPLYTA® supports the ultimate treatment goal of remission with robust short-term data and long-term open-label safety data

TITUSVILLE, NJ. (January 16, 2026) – Johnson & Johnson today announced a new analysis of Phase 3 data which found CAPLYTA® (lumateperone), in combination with an antidepressant, showed significantly greater remission rates in adults with major depressive disorder (MDD) than placebo plus an antidepressant at six weeks, with continued benefits observed through six months in an open-label extension study. The findings are featured in one of 11 abstracts from across Johnson & Johnson's neuropsychiatry portfolio that were presented at the 64th Annual Meeting of the American College of Neuropsychopharmacology (ACNP), held from January 12-15, in Nassau, Bahamas.

MDD is one of the most common psychiatric disorders, affecting about 22 million American adults.[1,2] While remission – relief from depressive symptoms – is the ultimate goal of treatment, nearly two-thirds of patients do not achieve it with available therapies. Patients with residual symptoms experience prolonged psychosocial impairment, higher relapse risk and overall reduced quality of life.[3] Beyond its toll on patients' well-being, MDD has a substantial economic burden and is the leading cause of disability in the U.S.[4]

CAPLYTA® may help patients achieve the goal of remission
To evaluate how CAPLYTA® may help patients achieve the goal of remission, the analysis draws from three Phase 3 CAPLYTA® studies, including pooled data from two pivotal efficacy and safety trials (Studies 501 and 502) and a six-month open-label extension safety study (Study 503).[5,6,7] The analysis evaluated three measures of remission, as defined by the Montgomery-Asberg Depression Rating Scale (MADRS): remission (defined as MADRS ≤10), complete remission (defined as MADRS ≤5), and sustained remission (defined as MADRS ≤10 maintained at each assessment) to assess the potential resolution and durability of relief from symptoms. Across all three measures, CAPLYTA® demonstrated meaningful remission rates, highlighting both the depth and durability of improvement for patients living with MDD.

"Today, remission is out of reach for the majority of patients with depression, which means they continue to struggle with persistent symptoms that negatively impact their daily lives," said Michael E. Thase, M.D., Professor of Psychiatry and Chief, Division of Mood and Anxiety Disorders Treatment & Research Program, Perelman School of Medicine at University of Pennsylvania.[8,9,a] "These data capture not only symptom reduction, but also the durability and depth of treatment response, which are critical benchmarks for patients and clinicians striving for lasting relief. The findings demonstrate that adjunctive lumateperone may almost double the likelihood of remission, with benefits sustained over six months, offering renewed hope to millions of adults seeking recovery from this disease.[1,2]"

Detailed study findings
In the pooled pivotal data, almost twice as many patients reached remission (MADRS ≤10) at six weeks with adjunctive CAPLYTA® compared to placebo (25.5 percent versus 13.6 percent; nominal p<0.0001), with 10.6 percent of patients achieving complete remission (MADRS ≤5) with CAPLYTA® plus an antidepressant compared to 5.6 percent with placebo plus an antidepressant (p<0.01). At six weeks, significantly greater remission rates with CAPLYTA® versus placebo were consistent across patient subgroups, including age, antidepressant type (SSRI/SNRI), and baseline severity.

In Study 503, a six-month open-label extension safety study (n = 809), efficacy was maintained with long-term CAPLYTA® treatment, with nearly two out of three patients (65.4 percent; n = 529) reaching remission (MADRS ≤10). Complete remission (MADRS ≤5) was reached by 44.1 percent (n = 357) of patients. Notably, almost half of patients (42.8 percent; n = 346) experienced sustained remission (MADRS ≤10 at each assessment) by the end of treatment, with rates increasing steadily throughout the study: Week 8 (28.6 percent; n = 231), Week 16 (37.2 percent; n = 301), and Week 24 (40.8 percent; n = 330). Remission rates were consistent across patient subgroups, including age, antidepressant type (SSRI/SNRI), and baseline severity.

"What matters most to patients isn't just an improvement in symptoms, but sustained relief that allows them to truly reclaim their lives," said Bill Martin, Ph.D., Global Therapeutic Area Head, Neuroscience, Johnson & Johnson Innovative Medicine. "Too many patients spend years cycling through treatments, settling for 'good enough' because they don't realize complete relief is possible. These data demonstrate that remission is within reach and should be the expectation, not the exception."

CAPLYTA® was recently approved by the U.S. Food and Drug Association (FDA) in November 2025 as an adjunctive therapy for MDD and is also indicated for the treatment of schizophrenia and depressive episodes associated with bipolar I or II disorder. While the mechanism of action is unknown, CAPLYTA® is characterized by high serotonin 5-HT_{2A} receptor occupancy and moderate amounts of dopamine D_2 receptor occupancy at therapeutic doses. CAPLYTA® does not need dose titration, allowing patients to start treatment at the effective dose of 42 mg.[3,10]

A supplemental New Drug Application (sNDA) for CAPLYTA® with long-term data evaluating the safety and efficacy of the medication for the prevention of relapse in schizophrenia was submitted to the FDA. The medication is also being studied for other neuropsychiatric disorders. CAPLYTA® is not FDA-approved for these disorders.

This press release is not sanctioned by ACNP.

Editor's note:
[a] Michael E. Thase, M.D. has provided consulting, advisory, and speaking services to Johnson & Johnson. He has not been paid for any media work.

About Major Depressive Disorder (MDD)
MDD is one of the most common psychiatric disorders and a leading cause of disability worldwide, impacting an estimated 332 million people – or about 4 percent of the population.[1] In the U.S. alone, about 22 million adults are living with the disease.[2] While depression is typically treated with a "one-size-fits-all" approach, no two cases are the same. MDD is a complex, heterogeneous disorder involving multiple regions of the brain and presenting with as many as 256 unique symptom combinations. As a result, responses to treatment vary widely.[11,12] Only 1 in 3 patients reach remission with their first antidepressant, and rates continue to decline further with each subsequent treatment – leaving many to spend years cycling through multiple treatments trying to find complete, sustained symptom relief.[8,9] Moreover, MDD is a risk factor for the development and worsening of a range of comorbidities, illustrating the importance of integrating mental and general health care.[13]

About Study 501 and Study 502
Studies 501 and 502 are two positive Phase 3 global, double-blind, placebo-controlled studies in patients with a primary diagnosis of MDD according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria who have had an inadequate response to ongoing antidepressant therapy. CAPLYTA®, added to an antidepressant, demonstrated robust efficacy for the treatment of MDD in the primary endpoint, the MADRS Total score, with a large separation versus placebo of 4.9 points (effect size 0.61) in Study 501 and 4.5 points (effect size 0.56) versus placebo in Study 502. The efficacy of CAPLYTA® is complemented with a favorable safety and tolerability profile – including a favorable metabolic, weight, and movement disorder profile. In the pooled safety data for Studies 501 and 502, the most commonly reported adverse events that were observed at a rate greater than or equal to 5% for lumateperone and greater than twice the rate of placebo were dizziness, dry mouth, somnolence/sedation, nausea, fatigue, and diarrhea. Importantly, metabolic and weight changes were similar to placebo and the rates of extrapyramidal symptoms were low.

About Study 503
Study 503 is a 26-week, open-label extension study that investigated the long-term safety of adjunctive CAPLYTA® 42mg in patients who completed Study 501 or 502. The primary endpoint was safety and tolerability of CAPLYTA®, measured by adverse events (AEs), extrapyramidal symptoms (EPS), suicidality, and changes in laboratory parameters, vital signs, and electrocardiogram (ECG) measures. The secondary endpoint was improvement/maintenance of depressive symptoms, measured by MADRS Total score and CGI-S score change from Study 501 or 502 baseline to Week 26 of open-label treatment. Mean changes from baseline to end of treatment were minimal for body morphology,

cardiometabolic laboratory values, prolactin levels, pulse rate, blood pressure, and ECG measures. During the 26-week safety study, 80% of patients responded to treatment and 65% of patients experienced remission (defined as MADRS Total score ≤ 10) at 6 months. No patients reported emergence of serious suicidal ideation or suicidal behavior during the study. Symptoms of depression improved as measured by mean change from baseline to Week 26 in MADRS Total score (−22.9) and CGI-S score (−2.7).

About CAPLYTA® (lumateperone)
CAPLYTA® 42 mg is an oral, once daily atypical antipsychotic approved in adults as an adjunctive therapy with antidepressants for major depressive disorder (MDD), schizophrenia, and depressive episodes associated with bipolar I or II disorder (bipolar depression), as monotherapy, and as adjunctive therapy with lithium or valproate.

While the mechanism of action of CAPLYTA® is unknown, the efficacy of CAPLYTA® could be mediated through a combination of antagonist activity at central serotonin 5-HT_{2A} receptors and partial agonist activity at central dopamine D_2 receptors.

INDICATIONS
CAPLYTA® (lumateperone) is a prescription medicine used in adults along with an antidepressant to treat major depressive disorder (MDD); to treat depressive episodes associated with bipolar I or bipolar II disorder (bipolar depression) alone or with lithium or valproate; or to treat schizophrenia. It is not known if CAPLYTA is safe and effective in children.

IMPORTANT SAFETY INFORMATION

Medicines like CAPLYTA can raise the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). CAPLYTA is not approved for treating people with dementia-related psychosis.

CAPLYTA and antidepressant medicines increase the risk of suicidal thoughts and actions in people 24 years of age and younger, especially within the first few months of treatment or when the dose is changed. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Patients and their families or caregivers should watch for new or worsening depression symptoms, especially sudden changes in mood, behaviors, thoughts, or feelings. This is very important when CAPLYTA or an antidepressant medicine is started or when the dose is changed. Report any changes in these symptoms to your healthcare provider immediately.

Do not take CAPLYTA if you are allergic to any of its ingredients. Get emergency medical help if you are having an allergic reaction (e.g., rash, itching, hives, swelling of the tongue, lip, face, or throat).

CAPLYTA may cause serious side effects, including:

- **Stroke (cerebrovascular problems)** in elderly people with dementia-related psychosis that can lead to death.
- **Neuroleptic malignant syndrome (NMS)**: high fever, confusion, changes in your breathing, heart rate, and blood pressure, stiff muscles, and increased sweating; these may be symptoms of a rare but potentially fatal condition. Contact your healthcare provider or go to the emergency room if you experience signs and symptoms of NMS.
- **Uncontrolled body movements (tardive dyskinesia, TD)** in your face, tongue, or other body parts. TD may not go away, even if you stop taking CAPLYTA. It may also occur after you stop taking CAPLYTA.
- **Problems with your metabolism** including high blood sugar, diabetes, increased fat (cholesterol and triglyceride) levels in your blood and weight gain. Your healthcare provider should check your blood sugar, fat levels, and weight before you start and during your treatment with CAPLYTA. Extremely high blood sugar levels can lead to coma or death. Call your healthcare provider if you have any of the following symptoms of high blood sugar: feeling very thirsty, hungry, sick to your stomach, needing to urinate more than usual, weak/tired, or confused, or your breath smells fruity.
- **Low white blood cell count**. Your healthcare provider may do blood tests during the first few months of treatment with CAPLYTA.
- **Decreased blood pressure (orthostatic hypotension)**. You may feel lightheaded, dizzy, or faint when you rise too quickly from a sitting or lying position.
- **Falls**. CAPLYTA may make you sleepy or dizzy, may cause a decrease in your blood pressure when changing position (orthostatic hypotension), and can slow your thinking and motor skills which may lead to falls that can cause broken bones or other injuries.
- **Seizures (convulsions).**
- **Sleepiness, drowsiness, feeling tired, difficulty thinking and doing normal activities.** Until you know how CAPLYTA affects you, do not drive, operate heavy machinery, or do other dangerous activities.

- **Problems controlling your body temperature so that you feel too warm**. Avoid getting overheated or dehydrated while taking CAPLYTA.
- **Difficulty swallowing that can cause food or liquid to get into the lungs.**

The most common side effects of CAPLYTA include sleepiness, dizziness, nausea, dry mouth, feeling tired, and diarrhea.

These are not all the possible side effects of CAPLYTA. Tell your healthcare provider if you have or have had heart problems or a stroke, high or low blood pressure, diabetes, or high blood sugar, problems with cholesterol, have or have had a low white blood cell count, seizures (convulsions), or kidney or liver problems.

CAPLYTA may cause fertility problems in females and males. You should notify your healthcare provider if you become pregnant or intend to become pregnant while taking CAPLYTA. There is a pregnancy registry for females who are exposed to CAPLYTA during pregnancy. CAPLYTA may cause abnormal involuntary movements and/or withdrawal symptoms in newborn babies exposed to CAPLYTA during the third trimester. Talk to your healthcare provider if you breastfeed or are planning to breastfeed as CAPLYTA passes into breast milk.

Tell your healthcare provider about all the medicines you're taking. CAPLYTA may affect the way other medicines work, and other medicines may affect how CAPLYTA works, causing possible serious side effects. Do not start or stop any medicines while taking CAPLYTA without talking to your healthcare provider. You are encouraged to report negative side effects of prescription drugs. Contact Intra-Cellular Therapies, Inc. at 1-888-611-4824 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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

US-CAP-2500827

Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for CAPLYTA.

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 https://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" as defined in the Private Securities Litigation Reform Act of 1995 related to product development and the potential benefits and treatment impact of CAPLYTA® (lumateperone). 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. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's most recent Annual Report on Form 10-K, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com, www.investor.jnj.com or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

Footnotes

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