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For Immediate Release

FDA approves CAPLYTA® (lumateperone) sNDA with robust new data supporting reduced risk of relapse in schizophrenia

CAPLYTA® reduced relapse risk by 63 percent, with 84 percent of patients with schizophrenia relapse-free over six months

Demonstrating long-term stability and a well-established safety profile consistent with previous CAPLYTA® studies

TITUSVILLE, N.J. (APRIL 27, 2026) – Johnson & Johnson announced today that the U.S. Food and Drug Administration (FDA) has approved a supplemental New Drug Application (sNDA) based on long-term data evaluating the safety and efficacy of CAPLYTA® (lumateperone) for the prevention of relapse in schizophrenia. The data further reinforces the long-term efficacy and tolerability of CAPLYTA® as the latest addition to Johnson & Johnson's leading portfolio of neuropsychiatric therapies.

Relapse is one of the most consequential challenges for people living with schizophrenia—disrupting stability, undermining functioning, and often triggering episodes of psychosis, hallucinations, and other symptoms that can derail daily life for patients and their loved ones.[i] Schizophrenia is a complex, chronic, and progressive condition affecting approximately 2.8 million adults in the United States, yet it remains significantly undertreated, with roughly 40 percent of individuals not receiving adequate care.[ii] On average, adults living with schizophrenia experience nine relapse episodes within a six-year period, which is why reducing relapse risk is a critical goal in long-term management, and can help preserve functioning, reduce caregiver and societal strain, and break the cycle of repeated hospitalization.[i,iii] Reducing relapse also mitigates the substantial economic burden associated with the disease, as the societal cost of schizophrenia in 2024 was estimated at $366.8 billion in the U.S.[iv, vi]

In the Phase 3, double-blind, randomized withdrawal trial supporting this update, CAPLYTA® significantly extended time to relapse versus placebo during the 26-week double-blind treatment period (p=0.0002), helping support long-term stability for adults living with schizophrenia. Patients who received CAPLYTA® had a 63 percent lower risk of relapse compared with placebo (hazard ratio = 0.37), and 84 percent of patients were relapse-free over six months. CAPLYTA® also significantly delayed time to all-cause treatment discontinuation, including relapse. The safety profile remained consistent with the existing body of clinical data, and no new safety concerns were identified. The most common treatment-related adverse event was headache, which occurred in at least 5 percent of patients and at least twice the rate of placebo.[v]

“Relapse can be one of the most disruptive aspects of schizophrenia, often undoing hard-won progress and increasing the risk of hospitalization,” said Christoph U. Correll, M.D., Clinical Professor of Psychiatry at the Zucker School of Medicine at Hofstra/Northwell, New York.[a] “These Phase 3 results—showing significantly longer time to relapse with 84% remaining relapse free over 6-months—provide clinicians with another tool that can offer long-term stability for people living with schizophrenia.”

While its exact 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. In schizophrenia short-term clinical studies, CAPLYTA® was similar to placebo in weight change, metabolic effects, and extrapyramidal symptoms, which are often cited as reasons for treatment discontinuation. In the Phase 3, 6-month randomized withdrawal, double-blind, placebo-controlled study, there were no clinically relevant increases in prolactin or cardiometabolic parameters at the end of the double-blind treatment period. Additionally, long-term data from a 12-month open-label extension study in schizophrenia showed that patients treated with CAPLYTA® experienced a mean weight change of –2.05 kg (–4.52 lbs.) over one year, with sustained

improvements or stability in metabolic parameters. CAPLYTA® makes it easy to start and stay on treatment without the need for titration.

"People living with schizophrenia deserve treatment options that help support stability over time, not just symptom control in the short term," said Celine Goldberger, MD, PhD, Vice President Global Medical Affairs, Neuroscience, Innovative Medicine, Johnson & Johnson. "This label update—backed by long-term Phase 3 data demonstrating a significant delay in time to relapse—reinforces our commitment to advancing evidence-based therapies to support each patient's individual needs including a proven therapy that supports stability over time."

CAPLYTA® (lumateperone) is FDA 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. This label update builds upon the existing clinical data and postmarketing experience across its approved uses. CAPLYTA® is also being evaluated in clinical studies for other neuropsychiatric and neurological conditions beyond its current FDA-approved indications.

Editor's note:

a. Christoph U. Correll, M.D., has provided consulting, advisory, and speaking services to Johnson & Johnson. He has not been paid for any media work.

About Schizophrenia
Schizophrenia is a complex, chronic brain disorder that affects how people think, feel, speak, and act. It affects up to an estimated 2.8 million adults in the United States yet remains widely misunderstood and insufficiently treated.[ii] Symptoms vary by person, but confusion and distortions in perceptions, emotions, and behavior are common. Evidence shows that the first three to five years after diagnosis — "the critical period" — from symptom onset are key for a patient's treatment, as this is when the condition progresses most rapidly.[vii,viii] A comprehensive treatment plan, which may include medication, therapy, and psychosocial services, can be critical in delaying the time to relapse for adults with schizophrenia.[i]

About Study 304
This study was a multicenter, multi-national, double-blind, placebo-controlled, randomized withdrawal study of lumateperone for the prevention of symptomatic relapse in adult patients with schizophrenia. The study included an 18-week open-label phase where patients with schizophrenia were treated with lumateperone 42 mg per day. Patients who met the stabilization criteria during the open-label period progressed to the double-blind treatment phase. These patients were randomized to continue on lumateperone 42 mg (N=110) or switch to placebo (N=114) for up to 26 weeks or until the time to relapse occurred. The primary endpoint was time to first symptom relapse and the key secondary endpoint was time to all cause discontinuation during the double-blind phase.

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 to treat: major depressive disorder (MDD) along with an antidepressant; depressive episodes associated with bipolar I or bipolar II disorder (bipolar depression) alone or with lithium or valproate; or schizophrenia.

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 click here to see full Prescribing Information including Boxed Warnings.

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

[i] Alphs L, et al. Factors associated with relapse in schizophrenia despite adherence to long-acting injectable therapy. Int Clin *Psychopharmacol*. 2016;31(4)202-209. doi:10.1097/YIC.0000000000000125

[ii] "Schizophrenia Fact Sheet." Treatment Advocacy Center, 10 Mar. 2025, www.tac.org/reports_publications/schizophrenia-fact-sheet/.

[iii] RWE IQVIA LAAD (Feb '18-Aug '25)

[iv] Velligan DI, Rao S. The epidemiology and global burden of schizophrenia. J Clin Psychiatry. 2023;84(1):MS21078COM5. Published January 2023. Accessed October 2025. Available at: https://www.psychiatrist.com/jcp/epidemiology-global-burden-schizophrenia/

[v] Intra-Cellular Therapies Announces Positive Topline Results in Phase 3 Trial Evaluating CAPLYTA for the Prevention of Relapse in Patients with Schizophrenia. *GlobeNewswire*, 05 Nov. 2024, https://www.globenewswire.com/news-release/2024/11/05/2974784/30597/en/Intra-Cellular-Therapies-Announces-Positive-Topline-Results-in-Phase-3-Trial-Evaluating-CAPLYTA-for-the-Prevention-of-Relapse-in-Patients-with-Schizophrenia.html.

[vi] Lafeuille MH, Gravel J, Lefebvre P, et al. Patterns of relapse and associated cost burden in schizophrenia patients receiving atypical antipsychotics. *J Med Econ*. 2013;16(11):1290-1299. doi: 10.3111/13696998.2013.841705

[vii] Birchwood, M. "Early intervention and sustaining the management of vulnerability." *The Australian and New Zealand journal of psychiatry* vol. 34 Suppl (2000): S181-4. doi:10.1080/000486700241

[viii] Tandon, Rajiv et al. "The schizophrenia syndrome, circa 2024: What we know and how that informs its nature." *Schizophrenia research* vol. 264 (2024): 1-28. doi:10.1016/j.schres.2023.11.015

US-CAP-2600335