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NEWS RELEASE

Johnson & Johnson elevates leadership in depression with new data at 2026 American College of Neuropsychopharmacology Annual Meeting

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New CAPLYTA® (lumateperone) Phase 3 analyses evaluating efficacy in achieving remission in adjunctive major depressive disorder (aMDD) to be presented

SPRAVATO® (esketamine) effects on anhedonia in treatment-resistant depression (TRD) – Phase 3 data post-hoc analyses to be presented

Comparative tolerability of adjunctive seltorexant vs. adjunctive quetiapine XR in major depressive disorder (MDD) with insomnia symptoms – new Phase 3 metabolic analyses will also be presented

TITUSVILLE, N.J., Jan. 13, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) announced today that 11 abstracts featuring new data on its robust portfolio and pipeline in neuropsychiatry will be presented at the 64th Annual Meeting of the American College of Neuropsychopharmacology (ACNP), held from January 12-15, in Nassau, Bahamas. Presentations include the latest research from across the Company's neuropsychiatry portfolio, including major depressive disorder (MDD) and treatment-resistant depression (TRD), as well as preclinical and translational neuropsychiatric research.

"At Johnson & Johnson, we are tackling the greatest unmet needs for patients living with depression, schizophrenia and bipolar disorder – with the ultimate goal of remission from disease," said Bill Martin, Ph.D., Global Therapeutic Area Head, Neuroscience, Johnson & Johnson Innovative Medicine. "Our data at ACNP this year showcases how we are boldly advancing our portfolio, from clinical findings on remission and tolerability to preclinical research on novel mechanisms and AI-driven precision tools, reflecting our commitment to redefining standards of care."

Key presentations include:

- A new analysis of Phase 3 clinical trials evaluating the efficacy of CAPLYTA® (lumateperone) in combination with antidepressants for remission of MDD symptoms in adults (Poster TH66).[1]
- New metabolic analyses of Phase 3 data evaluating the tolerability of seltorexant adjunctive to SSRI/SNRI, an investigational first-in-class therapy, compared to adjunctive quetiapine extended release (XR) in patients with MDD with insomnia symptoms (Poster TH67).[2]
- Findings from post-hoc analyses of two Phase 3 studies, TRANSFORM-2 and SUSTAIN-2, exploring the effects of SPRAVATO® (esketamine) CIII nasal spray on anhedonia in patients with TRD (Poster W123).[3]
- Preclinical and translational research showcasing novel AI platforms for precision medicine (Poster W117), investigating biology associated with neuropsychiatric diseases (Poster TU30), and early-stage work on new therapeutic mechanisms for depression (Poster TH202).[4,5,6]

Johnson & Johnson will present the following posters at the ACNP meeting on January 14 at 5:00 – 7:00 p.m. ET and January 15 at 5:00 – 7:00 p.m. ET in the Exhibit Halls:

Poster #	Title
Major Depressive Disorder	
TH66	Remission With Lumateperone 42 mg Adjunctive to Antidepressant Therapy in Patients With Major Depressive Disorder: Analysis of Short-Term and Long-Term Trials
W124	Efficacy of Lumateperone 42 mg for the Treatment of Major Depressive Disorder: Analysis of Demographic and Clinical Subgroups in a Phase 3 Randomized Placebo-Controlled Trial
W122	First Onset and Duration of Treatment-Emergent Adverse Events in Patients With Major Depressive Disorder Treated With Adjunctive Lumateperone 42 mg: A Pooled Analysis of 2 Randomized Placebo-Controlled Trials
TH67	Metabolic Profiles of Participants With Major Depressive Disorder With Insomnia Symptoms in a Phase 3 Trial of Seltorexant Versus Quetiapine Extended Release as Adjunctive Therapy
Treatment-Resistant Depression	
W123	Short- and Long-Term Effects of Esketamine Nasal Spray on Anhedonia in Treatment-Resistant Depression: Post-Hoc Analyses From Two Phase 3 Studies
Schizophrenia	
TH268	Characterization of Hippocampal E/I Balance in Novel Models of Schizophrenia and Pharmacological Intervention
TH245	Plasma Antipsychotic Levels in Remitted Patients with Schizophrenia Treated with Long-Acting Injectable Antipsychotics: Preliminary Results
TU30	Complement and Synaptic Protein Profiling in Schizophrenia CSF and Plasma: Analysis of the Psychiatric Biomarkers Network Cohort
Neuroscience Discovery	
TH41	Human iPSC-Derived Oligodendrocytes Implicate Maturation Deficits in Neuropsychiatric Disease
W117	NAIO (Neuroscience and AI-Optimized Platform): A Multi-Modal Computational Platform for Informing Target and Indication Selection, Biomarker Readout, and Patient Stratification in CNS Drug Development
TH202	Selective GluN2D Inhibition Recapitulates Non-Selective NMDAR Antagonists Effects on Synaptic Plasticity in Rodents

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.[7,8] In 2023, approximately 22 million adults in the U.S. had at least one major depressive episode.[9] 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.[10,11] As a result, responses to treatment vary widely. 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.[12] 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]

MDD often includes sleep disturbances such as insomnia or hypersomnia, with approximately 60 percent of MDD patients experiencing clinically relevant insomnia symptoms despite being on an SSRI/SNRI.[14] Disturbed sleep and insomnia symptoms have a significant impact on a patient's quality of life and exacerbate the risk of depressive relapse and suicide.[15,16]

Approximately one-third of adults with MDD will not respond to oral antidepressants alone and are considered to have treatment-resistant depression (TRD), which is often defined as inadequate response to two or more oral antidepressants that were administered at an adequate dose for an adequate duration.[17,18] TRD has a significant negative impact on the lives of those affected and has one of the highest economic burdens of all psychiatric disorders.[18] Patients often cycle through multiple oral medications, waiting 4-6 weeks for potential relief.[19] Based on the STAR*D study, after trying their third oral antidepressant, approximately 86 percent of patients do not achieve remission.[19]

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.

About Seltorexant

Seltorexant, an investigational first-in-class therapy, is a selective antagonist of the human orexin-2 receptor currently being developed as an adjunctive treatment for adults with MDD with insomnia symptoms. Seltorexant selectively antagonizes the orexin-2 receptors, potentially improving mood symptoms associated with depression and restoring sleep without next-day sedation in patients with depression.[20] When orexin-2 receptors are stimulated for too long or at inappropriate times, their activation can cause hyperarousal manifestations, including insomnia and excessive cortisol release, which may contribute to depression and insomnia.[21,22] Seltorexant is the only investigational therapy under study for the treatment of MDD that is believed to work by normalizing the overactivation of the orexin-2 receptors, thereby targeting the underlying biology that contributes to depression

and insomnia symptoms.

ABOUT SPRAVATO®

SPRAVATO® (esketamine) CIII nasal spray is approved by the U.S. Food and Drug Administration alone or in conjunction with an oral antidepressant for adults with MDD when they have inadequate response to at least two oral antidepressants (TRD) and depressive symptoms in adults with major depressive disorder with acute suicidal ideation or behavior in conjunction with an oral antidepressant. It is a non-selective, non-competitive antagonist of the N-methyl-D-aspartate (NMDA) receptor and is believed to work differently than traditional antidepressants by acting on a pathway in the brain that affects glutamate. The mechanism by which esketamine exerts its antidepressant effect is unknown. To date, SPRAVATO® has been approved in 79 markets and administered to more than 150,000 patients worldwide.

CAPLYTA® IMPORTANT SAFETY INFORMATION

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.

SPRAVATO® IMPORTANT SAFETY INFORMATION

What is SPRAVATO® (esketamine) CIII nasal spray?

SPRAVATO® is a prescription medicine used:

- with or without an antidepressant taken by mouth, to treat adults with treatment-resistant depression (TRD)
- with an antidepressant taken by mouth, to treat depressive symptoms in adults with major depressive disorder (MDD) with suicidal thoughts or actions

SPRAVATO® is not for use as a medicine to prevent or relieve pain (anesthetic). It is not known if SPRAVATO® is safe or effective as an anesthetic medicine.

It is not known if SPRAVATO® is safe and effective for use in preventing suicide or in reducing suicidal thoughts or actions. SPRAVATO® is not for use in place of hospitalization if your healthcare provider determines that hospitalization is needed, even if improvement is experienced after the first dose of SPRAVATO®.

It is not known if SPRAVATO® is safe and effective in children.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about SPRAVATO®?

SPRAVATO® can cause serious side effects, including:

- Sedation, dissociation, and respiratory depression. SPRAVATO® may cause sleepiness (sedation), fainting, dizziness, spinning sensation, anxiety, or feeling disconnected from yourself, your thoughts, feelings, space and time (dissociation), breathing problems (respiratory depression and respiratory arrest)
    - Tell your healthcare provider right away if you feel like you cannot stay awake or if you feel like you are going to pass out.
    - Your healthcare provider must monitor you for serious side effects for at least 2 hours after taking SPRAVATO®. Your healthcare provider will decide when you are ready to leave the healthcare setting.
- Abuse and misuse. There is a risk for abuse and misuse with SPRAVATO®, which may lead to physical and psychological dependence. Your healthcare provider should check you for signs of abuse, misuse, and dependence before and during treatment.
    - Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines, or street drugs.
    - Your healthcare provider can tell you more about the differences between physical and psychological dependence and drug addiction.
- SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS). Because of the risks for sedation, dissociation, respiratory depression and abuse and misuse, SPRAVATO® is only available through a restricted program called the SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS) Program. SPRAVATO® can only be administered at healthcare settings certified in the SPRAVATO® REMS Program. Patients treated in outpatient healthcare settings (such as medical offices and clinics) must be enrolled in the program.
- Increased risk of suicidal thoughts and actions. Antidepressant medicines may increase suicidal thoughts and actions in some people 24 years of age and younger, especially within the first few months of treatment or when the dose is changed. SPRAVATO® is not for use in children.
    - Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a higher risk of having suicidal thoughts or actions. These include people who have (or have a family history of) depression or a history of suicidal thoughts or actions.
- How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?
    - Pay close attention to any changes, especially sudden changes, in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions.
    - Tell your healthcare provider right away if you have any new or sudden changes in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions.

- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

Tell your healthcare provider or get emergency help right away if you or your family member have any of the following symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- new or worse depression
- feeling very agitated or restless
- trouble sleeping (insomnia)
- acting aggressive, being angry or violent
- an extreme increase in activity and talking (mania)
- suicide attempts
- new or worse anxiety
- panic attacks
- new or worse irritability
- acting on dangerous impulses
- other unusual changes in behavior or mood

Do not take SPRAVATO® if you:

- have blood vessel (aneurysmal vascular) disease (including in the brain, chest, abdominal aorta, arms and legs)
- have an abnormal connection between your veins and arteries (arteriovenous malformation)
- have a history of bleeding in the brain
- are allergic to esketamine, ketamine, or any of the other ingredients in SPRAVATO®.

If you are not sure if you have any of the above conditions, talk to your healthcare provider before taking SPRAVATO®.

Before you take SPRAVATO®, tell your healthcare provider about all of your medical conditions, including if you:

- have heart or brain problems, including:
  - high blood pressure (hypertension)
  - slow or fast heartbeats that cause shortness of breath, chest pain, lightheadedness, or fainting
  - history of heart attack
  - history of stroke
  - heart valve disease or heart failure
  - history of brain injury or any condition where there is increased pressure in the brain

- have liver problems
- have ever had a condition called "psychosis" (see, feel, or hear things that are not there, or believe in things that are not true).
- are pregnant or plan to become pregnant. SPRAVATO® may harm your unborn baby. You should not take SPRAVATO® if you are pregnant.
    - Tell your healthcare provider right away if you become pregnant during treatment with SPRAVATO®.
    - If you are able to become pregnant, talk to your healthcare provider about methods to prevent pregnancy during treatment with SPRAVATO®.
    - There is a pregnancy registry for women who are exposed to SPRAVATO® during pregnancy. The purpose of the registry is to collect information about the health of women exposed to SPRAVATO® and their baby. If you become pregnant during treatment with SPRAVATO®, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or online at **https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/.**
- are breastfeeding or plan to breastfeed. SPRAVATO® passes into your breast milk. You should not breastfeed during treatment with SPRAVATO®.

Tell your healthcare provider about all the medicines that you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Taking SPRAVATO® with certain medicine may cause side effects.

Especially tell your healthcare provider if you take central nervous system (CNS) depressants, psychostimulants, or monoamine oxidase inhibitors (MAOIs) medicines. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

How will I take SPRAVATO®?

- You will take SPRAVATO® nasal spray yourself, under the supervision of a healthcare provider in a healthcare setting. Your healthcare provider will show you how to use the SPRAVATO® nasal spray device.
- Your healthcare provider will tell you how much SPRAVATO® you will take and when you will take it.
- Follow your SPRAVATO® treatment schedule exactly as your healthcare provider tells you to.
- During and after each use of the SPRAVATO® nasal spray device, you will be checked by a healthcare provider who will decide when you are ready to leave the healthcare setting.
- You will need to plan for a caregiver or family member to drive you home after taking SPRAVATO®.
- If you miss a SPRAVATO® treatment, your healthcare provider may change your dose and treatment schedule.

- Some people taking SPRAVATO® get nausea and vomiting. You should not eat for at least 2 hours before taking SPRAVATO® and not drink liquids at least 30 minutes before taking SPRAVATO®.
- If you take a nasal corticosteroid or nasal decongestant medicine take these medicines at least 1 hour before taking SPRAVATO®.

What should I avoid while taking SPRAVATO®?

Do not drive, operate machinery, or do anything where you need to be completely alert after taking SPRAVATO®. Do not take part in these activities until the next day following a restful sleep. See "What is the most important information I should know about SPRAVATO®?"

What are the possible side effects of SPRAVATO®?

SPRAVATO® may cause serious side effects including:

See "What is the most important information I should know about SPRAVATO®?"

Increased blood pressure. SPRAVATO® can cause a temporary increase in your blood pressure that may last for about 4 hours after taking a dose. Your healthcare provider will check your blood pressure before taking SPRAVATO® and for at least 2 hours after you take SPRAVATO®. Tell your healthcare provider right away if you get chest pain, shortness of breath, sudden severe headache, change in vision, or seizures after taking SPRAVATO®.

Problems with thinking clearly. Tell your healthcare provider if you have problems thinking or remembering.

Bladder problems. Tell your healthcare provider if you develop trouble urinating, such as a frequent or urgent need to urinate, pain when urinating, or urinating frequently at night.

The most common side effects of SPRAVATO® include:

- feeling disconnected from yourself, your thoughts, feelings and things around you
- dizziness
- nausea
- feeling sleepy
- spinning sensation
- decreased feeling of sensitivity (numbness)
- feeling anxious
- lack of energy
- increased blood pressure
- vomiting
- feeling drunk
- headache
- feeling very happy or excited

If these common side effects occur, they usually happen right after taking SPRAVATO® and go away the same day.

These are not all the possible side effects of SPRAVATO®.

Call your doctor for medical advice about side effects. You may report side effects to Johnson & Johnson at 1-800-526-7736, or to the FDA at 1-800-FDA-1088.

Please see full **Prescribing Information**, including Boxed WARNINGS, and **Medication Guide** for SPRAVATO® and discuss any questions you may have with your healthcare provider.

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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), SPRAVATO® (esketamine) CIII nasal spray, and seltorexant. 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.

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