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NEWS RELEASE

# Johnson & Johnson spotlights new neuropsychiatry data across bipolar mania, depression and schizophrenia at Psych Congress 2026

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First presentation of pivotal Phase 3 CAPLYTA ® data in adults with bipolar mania underscores the asset's potential across mood disorders

New SPRAVATO ® analyses and schizophrenia research emphasize a focus on complex, high-burden neuropsychiatric conditions

TITUSVILLE, N.J., Sept. 8, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced that 24 abstracts featuring clinical data and real-world evidence across the neuropsychiatry portfolio will be presented at the 2026 Psych Congress Annual Meeting (September 15-19, New Orleans, LA).

Among the featured presentations are new pivotal Phase 3 data evaluating the efficacy and safety of CAPLYTA® (lumateperone) in bipolar mania, alongside additional CAPLYTA® data across bipolar depression and major depressive disorder that further reinforce the breadth of studies for the asset across mood disorders. Data evaluating the effect of SPRAVATO® (esketamine) CIII nasal spray on depressive symptoms such as anhedonia, and Phase 3 clinical trial data for seltorexant in major depressive disorder (MDD) with insomnia symptoms will also be presented. Together, the presentations reflect the Company's continued commitment to advancing research across mood disorders, with a focus on areas where patients and clinicians still face significant treatment challenges.

"People living with neuropsychiatric disorders often face complex, overlapping symptoms that can make identification, treatment selection and long-term management especially challenging," said Jane Tiller, MD, Vice President, Global Head of Development, Neuroscience, Johnson & Johnson. "By advancing clinical and real-world

evidence across our portfolio and pipeline, we aim to help move psychiatry forward so that clinicians can continue to make more informed decisions for the patients they serve."

## Psych Congress Annual Meeting highlights include:

- CAPLYTA®
  - New data from a pivotal Phase 3 study investigating CAPLYTA® in the acute treatment of patients with manic episodes or manic episodes with mixed features associated with bipolar I disorder will be presented,[1] alongside additional data evaluating adjunctive CAPLYTA® in MDD across depressive symptoms, remission, patient subgroups, and metabolic outcomes.[2-8]
  - New real-world evidence study evaluating treatment patterns among patients with bipolar depression receiving CAPLYTA®, including dosing and duration in line with routine clinical practice.[9]
- SPRAVATO®
  - New analyses examining real-world evidence on the impact of SPRAVATO® in treating anhedonia, a core symptom of depression associated with poorer treatment outcomes.[10,11]
- Long-acting Injectables (LAIs)
  - Real-world studies evaluating schizophrenia-related hospitalizations in young dual-eligible patients prior to LAI initiation and subsequent risk of relapse, as well as treatment satisfaction with LAIs.[12,13]
- Seltorexant
  - Real-world data providing insights into MDD with insomnia symptoms, including disease burden, patient management and treatment outcomes.[14-16]

The full list of Johnson & Johnson data presentations at Psych Congress is available on **JNJ.com**. The Company will also support a variety of educational programs, in-booth presentations and training opportunities for attendees, including interactive visualizations of PRIDE LAI data, and the latest CAPLYTA® schizophrenia and network meta-analysis (NMA) findings.

## ABOUT BIPOLAR MANIA

Bipolar disorder affects an estimated 37 million people worldwide—approximately 1 in 200 individuals—with 4.4% of U.S. adults experiencing the condition in their lifetime.[17,18] Mania, a key feature of Bipolar I disorder, is characterized by at least a week-long period of elevated or irritable mood and/or increased energy, as well as symptoms including grandiosity, decreased need for sleep, racing thoughts, distractibility, and risk-taking behavior.[19] These noticeable behavioral changes often differ markedly from an individual's baseline and are frequently first recognized by those close to them. In severe cases, manic episodes may require hospitalization for safety and treatment.[20]

## 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.[21,22,23] In 2023, approximately 22 million adults in the U.S. had at least one major depressive episode.[24] 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.[25,26] 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.[27] 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.[28]

Anhedonia, a loss of interest or pleasure in previously enjoyed activities, is one of two defining symptoms of a major depressive episode.[29] Anhedonia is associated with poorer treatment outcomes, including lower remission rates, greater functional impairment, and higher suicide risk.[30] Notably, 40-70% of people with MDD experience anhedonia.[30]

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.[31] 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.[32,33]

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.[34,35] TRD has a significant negative impact on the lives of those affected and has one of the highest economic burdens of all psychiatric disorders.[35] Patients often cycle through multiple oral medications, waiting 4-6 weeks for potential relief.[36] Based on the STAR*D study, after their third line of treatment, approximately 86 percent of patients do not achieve remission.[36]

## 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.[37] Symptoms vary by person, but confusion and distortions in perceptions, emotions, and behavior are common.[38] 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.[39,40] A comprehensive treatment plan, which may include medication, therapy, and psychosocial services, is critical in delaying the time to

relapse for adults with schizophrenia.[41]

## 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, or 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.

A supplemental New Drug Application (sNDA) for CAPLYTA® with long-term data evaluating the safety and efficacy of the medication for delayed time to relapse in schizophrenia was recently **approved** by the U.S. Food and Drug Administration. The medication is also being studied for other neuropsychiatric disorders. CAPLYTA® is not FDA-approved for these disorders.

## ABOUT SPRAVATO® (esketamine) CIII NASAL SPRAY

SPRAVATO® is approved by the U.S. Food and Drug Administration as monotherapy 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 over 70 markets and administered to more than 250,000 patients worldwide.

## ABOUT J&J'S SCHIZOPHRENIA LONG-ACTING INJECTABLE (LAI) PORTFOLIO

Johnson & Johnson's portfolio of long-acting injectable (LAI) offerings for schizophrenia offers a varied range of dosing options and the longest-lasting schizophrenia treatments with each dose available, including INVEGA SUSTENNA® (1-month paliperidone palmitate), INVEGA TRINZA® (3-month paliperidone palmitate), and INVEGA HAFYERA® (6-month paliperidone palmitate), all of which are administered in a clinical setting by a medical professional.[42,43,44]

## 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.[45] 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.[46,47] 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.

## CAPLYTA® IMPORTANT SAFETY INFORMATION

### What is CAPLYTA (lumateperone)?

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

### What is the most important information I should know about CAPLYTA?

- 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.

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

**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).

## What are the possible side effects of CAPLYTA?

## 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.

Before taking CAPLYTA, tell your healthcare provider about all of your medical conditions, including 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 1-800-526-7736 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.

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

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## INVEGA SUSTENNA®, INVEGA TRINZA®, INVEGA HAFYERA® IMPORTANT SAFETY INFORMATION

### INDICATIONS

INVEGA HAFYERA® (6-month paliperidone palmitate) is a prescription medicine given by injection every 6 months by a healthcare professional and used to treat schizophrenia. INVEGA HAFYERA® is used in adults who have been treated with either:

- INVEGA SUSTENNA® (paliperidone palmitate) a 1-time-each-month paliperidone palmitate extended-release injectable suspension for at least 4 months

- INVEGA TRINZA® (paliperidone palmitate) a 1-time-every-3-months paliperidone palmitate extended-release injectable suspension for at least 3 months

INVEGA TRINZA® is a prescription medicine given by injection every 3 months by a healthcare professional and used to treat schizophrenia. INVEGA TRINZA® is used in people who have been adequately treated with INVEGA SUSTENNA® for at least 4 months.

INVEGA SUSTENNA® is a prescription medicine given by injection by a healthcare professional.

INVEGA SUSTENNA® is used to treat schizophrenia in adults.

## IMPORTANT SAFETY INFORMATION

### What is the most important information I should know about INVEGA HAFYERA®, INVEGA TRINZA® and INVEGA SUSTENNA®?

### INVEGA HAFYERA®, INVEGA TRINZA® and INVEGA SUSTENNA® may cause serious side effects, including:

- Increased risk of death in elderly people with dementia-related psychosis.
  INVEGA HAFYERA®, INVEGA TRINZA® and INVEGA SUSTENNA® increase the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). INVEGA HAFYERA®, INVEGA TRINZA® and INVEGA SUSTENNA® are not for the treatment of people with dementia-related psychosis.

### Do not receive INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA® if you are

allergic to paliperidone, paliperidone palmitate, risperidone, or any of the ingredients in INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA®. See the end of the Patient Information leaflet in the full Prescribing Information for a complete list of INVEGA HAFYERA®, INVEGA TRINZA® and INVEGA SUSTENNA® ingredients.

### Before you receive INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA®

, tell your healthcare professional about all your medical conditions, including if you:

- have had Neuroleptic Malignant Syndrome (NMS)
- have or have had heart problems, including a heart attack, heart failure, abnormal heart rhythm, or long QT syndrome
- have or have had low levels of potassium or magnesium in your blood
- have or have had uncontrolled movements of your tongue, face, mouth, or jaw (tardive dyskinesia)

- have or have had kidney or liver problems
- have diabetes or have a family history of diabetes
- have Parkinson's disease or a type of dementia called Lewy Body Dementia
- have had a low white blood cell count
- have had problems with dizziness or fainting or are being treated for high blood pressure
- have or have had seizures or epilepsy
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA® will harm your unborn baby
    - If you become pregnant while taking INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA®, talk to your healthcare professional about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or visit **http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry**.
    - Infants born to women who are treated with INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA® may experience symptoms such as tremors, irritability, excessive sleepiness, eye twitching, muscle spasms, decreased appetite, difficulty breathing, or abnormal movement of arms and legs. Let your healthcare professional know if these symptoms occur.
- are breastfeeding or plan to breastfeed. INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA® can pass into your breast milk. Talk to your healthcare professional about the best way to feed your baby if you receive INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA®.

Tell your healthcare professional about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. INVEGA HAFYERA®, INVEGA TRINZA® and INVEGA SUSTENNA® may affect the way other medicines work, and other medicines may affect how INVEGA HAFYERA®, INVEGA TRINZA® and INVEGA SUSTENNA® works.

Your healthcare provider can tell you if it is safe to receive INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA® with your other medicines. Do not start or stop any medicines during treatment with INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA® without talking to your healthcare provider first. Know the medicines you take. Keep a list of them to show to your healthcare professional or pharmacist when you get a new medicine.

Patients (particularly the elderly) taking antipsychotics with certain health conditions or those on long-term therapy should be evaluated by their healthcare professional for the potential risk of falls.

## How will I receive INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA®?

- Follow your treatment schedule exactly as your healthcare provider tells you to.
- Your healthcare provider will tell you how much you will receive and when you will receive it.

## What should I avoid while receiving INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA®?

- INVEGA HAFYERA®, INVEGA TRINZA® and INVEGA SUSTENNA® may affect your ability to make decisions, think clearly, or react quickly. Do not drive, operate heavy machinery, or do other dangerous activities until you know how INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA® affects you.
- Avoid getting overheated or dehydrated.

## INVEGA HAFYERA®, INVEGA TRINZA® and INVEGA SUSTENNA® may cause serious side effects, including:

- See "What is the most important information I should know about INVEGA HAFYERA®, INVEGA TRINZA® and INVEGA SUSTENNA®?"
- stroke in elderly people (cerebrovascular problems) that can lead to death
- Neuroleptic Malignant Syndrome (NMS). NMS is a rare but very serious problem that can happen in people who receive INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA®. NMS can cause death and must be treated in a hospital. Call your healthcare professional right away if you become severely ill and have any of these symptoms: high fever; severe muscle stiffness; confusion; loss of consciousness; changes in your breathing, heartbeat, and blood pressure.
- problems with your heartbeat. These heart problems can cause death. Call your healthcare professional right away if you have any of these symptoms: passing out or feeling like you will pass out, dizziness, or feeling as if your heart is pounding or missing beats.
- uncontrolled movements of your tongue, face, mouth, or jaw (tardive dyskinesia)
- metabolic changes. Metabolic changes may include high blood sugar (hyperglycemia), diabetes mellitus and changes in the fat levels in your blood (dyslipidemia), and weight gain.
- low blood pressure and fainting
- changes in your blood cell counts
- high level of prolactin in your blood (hyperprolactinemia). INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA® may cause a rise in the blood levels of a hormone called prolactin (hyperprolactinemia) that may cause side effects including missed menstrual periods, leakage of milk from the breasts, development of breasts in men, or problems with erection.
- problems thinking clearly and moving your body
- seizures
- difficulty swallowing that can cause food or liquid to get into your lungs

- prolonged or painful erection lasting more than 4 hours. Call your healthcare professional or go to your nearest emergency room right away if you have an erection that lasts more than 4 hours.
- problems with control of your body temperature, especially when you exercise a lot or spend time doing things that make you warm. It is important for you to drink water to avoid dehydration.

The most common side effects of INVEGA HAFYERA® include: injection site reactions, weight gain, headache, upper respiratory tract infections, feeling restlessness or difficulty sitting still, slow movements, tremors, stiffness and shuffling walk.

The most common side effects of INVEGA TRINZA® include: injection site reactions, weight gain, headache, upper respiratory tract infections, feeling restlessness or difficulty sitting still, slow movements, tremors, stiffness and shuffling walk.

The most common side effects of INVEGA SUSTENNA® include: injection site reactions; sleepiness or drowsiness; dizziness; feeling of inner restlessness or needing to be constantly moving; abnormal muscle movements, including tremor (shaking), shuffling, uncontrolled involuntary movements, and abnormal movements of your eyes.

Tell your healthcare professional if you have any side effect that bothers you or does not go away. These are not all the possible side effects of INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA®. For more information, ask your healthcare professional or pharmacist.

Call your healthcare professional for medical advice about side effects. You may report side effects of prescription drugs to the FDA at 1-800-FDA-1088.

## General information about the safe and effective use of INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA®

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet.

Do not use INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA® for a condition for which it was not prescribed. You can ask your pharmacist or healthcare professional for information about INVEGA HAFYERA®, INVEGA TRINZA® or INVEGA SUSTENNA® that is written for healthcare professionals.

For more information, go to **www.invegahafyera.com**, **www.invegatrinza.com** or **www.invegasustenna.com** or call **1-800-526-7736**.

Please click to read the full Prescribing Information, including Boxed WARNING, for **INVEGA HAFYERA®**, **INVEGA TRINZA®** and **INVEGA SUSTENNA®** and discuss any questions you have with your healthcare professional.

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## 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:

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- thoughts about suicide or dying
- new or worse depression
- feeling very agitated or restless
- trouble sleeping (insomnia)
- acting aggressive, being angry or violent
- suicide attempts
- new or worse anxiety
- panic attacks
- new or worse irritability
- acting on dangerous impulses

- an extreme increase in activity and talking (mania)
- 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 medicines 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:

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- 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.

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## 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.

## References:

Brown D, Chen C, Chen M, et al. Lumateperone Treatment for Manic Episodes or Manic Episodes With Mixed Features in Bipolar I Disorder: Results From a Double-Blind, Placebo-Controlled, Randomized, Phase 3 Trial. Psych Congress 2026 Annual Meeting; Sept. 15-19, 2026.
Black D, Namjoshi M, Obando C, et al. Changes in Mean Total Score on the PHQ-9 Among Bipolar Depression Patients Treated with Lumateperone in the United States: An Electronic Health Records Study. Psych Congress 2026 Annual Meeting; Sept. 15-19, 2026.
Chen C, Durgam S, Earley WR, et al. Adjunctive Lumateperone 42 mg Treatment in Major Depressive Disorder: A Pooled Analysis of Efficacy Across Patient-Reported Depression Symptoms. Psych Congress 2026 Annual Meeting; Sept. 15-19, 2026.
Armas-Datorre J, Durgam S, Earley WR, et al. Lumateperone 42 mg in Major Depressive Disorder: Demographic and Clinical Subgroups Efficacy Analysis in a Phase 3 Randomized Placebo-Controlled Trial. Psych Congress 2026 Annual Meeting; Sept. 15-19, 2026.
Bhagwagar Z, Chen C, Durgam S, et al. Lumateperone 42 mg in Patients With Major Depressive Disorder: Analysis of Remission in Short- and Long-Term Trials. Psych Congress 2026 Annual Meeting; Sept. 15-19, 2026.
Dutheil S, Snyder G. Assessment of Lumateperone Partial Agonist Activity at Presynaptic Dopamine $D_2$ Autoreceptors: Reversal of Haloperidol-Induced Tyrosine Hydroxylase Phosphorylation in Mouse Striatum. Psych Congress 2026 Annual Meeting; Sept. 15-19, 2026.
Chepke C, Durgam S, Earley W, et al. Metabolic Profile of Adjunctive Lumateperone 42 mg in Major Depressive Disorder: A Pooled Analysis of 2 Randomized, Placebo-Controlled Trials. Psych Congress 2026 Annual Meeting; Sept. 15-19, 2026.
Chen H, Namjoshi M, Wu E, et al. Total Cost per Remitter of Lumateperone Versus Cariprazine for the Treatment of Major Depressive Disorder in the United States. Psych Congress 2026 Annual Meeting; Sept. 15-19, 2026.
Liu Z, Namjoshi M, Obando C, et al. Real-World Lumateperone Dosing Patterns and Treatment Duration in Bipolar Depression. Psych Congress 2026 Annual Meeting; Sept. 15-19, 2026.
Chepke C, Fu DJ, Himedan M, et al. Montgomery-Åsberg Depression Rating Scale Anhedonia Factor Score Following Esketamine Nasal Spray Monotherapy in Adult Patients With Treatment-Resistant Depression: A Post Hoc Analysis. Psych Congress 2026 Annual Meeting; Sept. 15-19, 2026.
Cutler AJ, Drzayich J, Fu DJ, et al. Esketamine Nasal Spray on Anhedonia and Functional Outcomes: Findings from the Ventura Real-World Evidence Study. Psych Congress 2026 Annual Meeting; Sept. 15-19, 2026.
Benson C, Doshi J, Geng Z, et al. Association of Schizophrenia-Related Hospitalization Before Long-Acting Injectable Antipsychotic Initiation and Outcomes Among Young Dual Eligibles. Psych Congress 2026 Annual Meeting; Sept. 15-19, 2026.
Citrome L, Cline F, Han J, et al. Treatment Satisfaction, Quality of Life, Satisfaction with Participation in Social Roles, and Caregiver Burden In Adults with Schizophrenia Treated with Paliperidone Palmitate Long-Acting Injectables. Psych Congress 2026 Annual Meeting; Sept. 15-19, 2026.

Cambron-Mellott J, Dwibedi N, Hamilton J, et al. Incidence of cardiometabolic events among adults with major depressive disorder with and without insomnia symptoms: a real-world evidence study. Psych Congress 2026 Annual Meeting; Sept. 15-19, 2026.
Benson C, Campbell A, Johnston K, et al. Association of Insomnia Symptoms in Major Depressive Disorder with Healthcare Resource Use and Cardiovascular and Metabolic Conditions - Analysis of National Health & Nutrition Examination Survey. Psych Congress 2026 Annual Meeting; Sept. 15-19, 2026.
Creel S, Hebert Z, Johnston K, et al. Understanding Insomnia Management in Major Depressive Disorder Through Patient-Provider Discourse. Psych Congress 2026 Annual Meeting; Sept. 15-19, 2026.
World Health Organization. Bipolar disorder. September 2025. Accessed August 2026. **https://www.who.int/news-room/fact-sheets/detail/bipolar-disorder**
National Health Institute. Bipolar Disorder. Accessed August 2026. **https://www.nimh.nih.gov/health/statistics/bipolar-disorder#part_2606**
Oliva V, Fico G, De Prisco M et al. Bipolar disorders: an update on critical aspects. Lancet Reg Health Eur. 2024;48. doi:10.1016/j.lanepe.2024.101135.
Cleveland Clinic. Mania. April 2026. Accessed August 2026. **https://my.clevelandclinic.org/health/diseases/21603-mania**
World Health Organization. Mental disorders. Accessed May 2026. **https://www.who.int/news-room/fact-sheets/detail/mental-disorders**
National Alliance on Mental Health. Mental health by the numbers. Accessed May 2026. **https://www.nami.org/mental-health-by-the-numbers/**
World Health Organization. Depressive disorder (depression). Accessed October 2025. who.int/news-room/fact-sheets/detail/depression
Key substance use and mental health indicators in the United States: results from the 2023 national survey on drug use and health. Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Published July 2024. Accessed May 2026. **https://www.samhsa.gov/data/report/2023-nsduh-annual-national-report**
Su YA and Si T. Progress and challenges in research of the mechanisms of anhedonia in major depressive disorder. Gen Psychiatr. 2022;35:e100724. doi:10.1136/gpsych-2021-10072
Pandya M, et al. Where in the Brain Is Depression? Curr Psychiatry Rep. 2012;14:634–642. doi:10.1007/s11920-012-0322-7
Rush AJ, Trivedi MH, Wisniewski SR, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. Am J Psychiatry. 2006 Nov;163(11):1905-17. doi:10.1176/ajp.2006.163.
Arnaud AM, Brister TS, Duckworth K, et al. Impact of major depressive disorder on comorbidities: a systematic literature review. J Clin Psychiatry. 2022;83(6):21r14328.
Cao B, Zhu J, Zuckerman H, et al. Pharmacological interventions targeting anhedonia in patients with major depressive disorder: A systematic review. Prog Neuropsychopharmacol Biol Psychiatry. 2019;92:109–117. doi:

10.1016/j.pnpbp.2019.01.002
Kale H, Ganz ML, Ghosh, R. Burden of prominent anhedonia in major depressive disorder reflected in polypharmacy, healthcare use and humanistic outcomes. Poster presentation at Psych Congress 2024, Boston, MA, United States.
Ohayon MM, Roth T. Place of chronic insomnia in the course of depressive and anxiety disorders. J Psychiatr Res. 2003;37(1):9-15. doi:10.1016/S0022-3956(02)00052-3
Taddei-Allen P. Economic Burden and Managed Care Considerations for the Treatment of Insomnia. AJMC. Updated April 12, 2020. Accessed May 2026. **https://www.ajmc.com/view/economic-burden-and-managed-care-considerations-for-the-treatment-of-insomnia**
Ağargün MY, Kara H, Solmaz M. Sleep disturbances and suicidal behavior in patients with major depression. J Clin Psychiatry. 1997;58(6):249-51
National Institute of Mental Health. Major Depression. Accessed May 2026. **https://www.nimh.nih.gov/health/statistics/major-depression**
Zhdanava M, Pilon D, Ghelerter I, et al. The prevalence and national burden of treatment-resistant depression and major depressive disorder in the United States. J Clin Psychiatry. 2021;82(2):20m13699. doi:10.4088/JCP.20m13699
Sanacora G, Zarate C, Krystal J, et al. Targeting the glutamatergic system to develop novel, improved therapeutics for mood disorders. Nat Rev Drug Discov. 2008;7(5):426-437. doi:10.1038/nrd2462
Treatment Advocacy Center. Schizophrenia Fact Sheet. Accessed May 2026. **www.tac.org/reports_publications/schizophrenia-fact-sheet/**.
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
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
National Alliance on Mental Illness. Understanding Schizophrenia. Accessed May 2026. **https://www.nami.org/types-of-conditions/schizophrenia/**
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
INVEGA SUSTENNA® [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.
INVEGA TRINZA® [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.
INVEGA HAFYERA® [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.
Recourt K, de Boer P, Zuiker R, et al. The selective orexin-2 antagonist seltorexant (JNJ-42847922/MIN-202) shows antidepressant and sleep-promoting effects in patients with major depressive disorder [published correction appears in Transl Psychiatry. 2019 Oct 2;9(1):240. doi:10.1038/s41398-019-0585-4
Nollet M, Leman S. Role of orexin in the pathophysiology of depression: potential for pharmacological intervention. CNS Drugs. 2013;27(6):411-422. doi:10.1007/s40263-013-0064-z
Brooks S, Jacobs GE, de Boer P, et al. The selective orexin-2 receptor antagonist seltorexant improves sleep: An

exploratory double-blind, placebo controlled, crossover study in antidepressant-treated major depressive disorder patients with persistent insomnia. J Psychopharmacol. 2019;33(2):202-209. doi:10.1177/0269881118822258

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