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NEWS RELEASE

Johnson & Johnson to highlight breadth of its major depressive disorder portfolio at 2025 ECNP Congress

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17 abstracts from across the Company's portfolio and pipeline highlight new clinical and real-world data on major depressive disorder and treatment-resistant depression

New post-hoc analysis of CAPLYTA® (lumateperone) Phase 3 data evaluates the impact on sexual function in MDD, reinforcing potential to reset treatment expectations

European Union and United Kingdom sub-group analyses of Phase 3 data evaluate efficacy of adjunctive seltorexant compared to adjunctive quetiapine XR in MDD with insomnia symptoms

New data from post-hoc analysis of ESCAPE-TRD explores association of patient characteristics and remission with SPRAVATO® (esketamine) versus quetiapine XR in treatment-resistant depression

TITUSVILLE, N.J., Oct. 10, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) announced today that 17 abstracts featuring new clinical and real-world data will be presented at the annual European College of Neuropsychopharmacology (ECNP) Congress, taking place October 11-14 in Amsterdam, The Netherlands. Presentations include the latest research from across the Company's neuropsychiatry portfolio, including major depressive disorder (MDD), treatment-resistant depression (TRD), and schizophrenia.

"MDD is a complex disorder that can manifest in different ways for each individual, and the traditional one-size-fits-all treatment approach often results in mixed patient outcomes," said Bill Martin, Ph.D., Global Neuroscience Therapeutic Area Head, Johnson & Johnson Innovative Medicine.[1,2] "At Johnson & Johnson, we are committed to advancing innovative and differentiated therapies through a targeted and patient-first approach, and our data at ECNP strongly reflects our relentless focus on this commitment."

Key presentations include:

- New analysis of Phase 3 data evaluating the impact of investigational adjunctive CAPLYTA® (lumateperone) on sexual function in patients with MDD (Poster PS04-3102).[3]
- An oral presentation highlighting findings from a sub-group analysis of Phase 3 data evaluating the efficacy of adjunctive seltorexant, an investigational first-in-class therapy, compared with adjunctive quetiapine extended release (XR) in European Union and United Kingdom patients with MDD with insomnia symptoms.[4]
- Findings from a post-hoc analysis of the ESCAPE-TRD study examining the association between baseline patient characteristics and reaching remission with SPRAVATO® (esketamine) CIII nasal spray versus quetiapine XR in patients with TRD (Poster PS02-1219).[5]
- Real-world safety data from the French ELLIPSE study of SPRAVATO® (PS02-1111).[6]
- Results from a Delphi research study outlining expert consensus recommendations of European psychiatrists on key decision-making factors for continuation of SPRAVATO® treatment in patients with TRD (Poster PS04-3215).[7]

Johnson & Johnson will present the following posters at ECNP Congress on October 12 from 8:00 – 8:30 a.m. CET (e-posters), October 13 from 12:35 – 2:00 p.m. CET, and October 14 from 12:35 – 2:00 p.m. CET.

Poster #	Title
Major Depressive Disorder	
EP03-0245	Adjunctive Lumateperone 42 mg Treatment in Major Depressive Disorder: Efficacy in Anhedonia and Across Broad Range of Depressive Symptoms
PS03-2109	Efficacy of Adjunctive Lumateperone 42 mg Treatment Across Depression and Anhedonia Symptoms in Major Depressive Disorder
PS04-3102	Evaluation of Sexual Function With Adjunctive Lumateperone in Patients With Major Depressive Disorder
EP03-0243	Long-Term Adjunctive Lumateperone Treatment in Major Depressive Disorder: Results From a Six-Month Open-Label Extension Study
PS03-2108	Beyond Inflammation: Unveiling Novel Molecular Mechanisms in Major Depressive Disorder and Antidepressant Response in a Cohort Stratified by Inflammatory Status
PS02-1123	Seltorexant: A Safe and Well-Tolerated Adjunctive Treatment for Adolescent Major Depressive Disorder With Comparable Pharmacokinetics to Adults
PS03-2143	Factors Associated With Long-Term Hypnotics Use in Depression
Oral Presentation	Developments in Adjunctive Treatment: Seltorexant Versus Quetiapine in Managing Major Depressive Disorder With Insomnia Symptoms
Treatment-Resistant Depression	
PS02-1220	Efficacy and Safety of 4 Months of Treatment With Esketamine Nasal Spray Monotherapy in Adult Patients With Treatment-Resistant Depression
PS01-0124	Early Dose Management and Up-Titration of Esketamine in the Double-Blind Induction Phase of the Randomized, Active-Controlled, Phase 3 TRANSFORM-2 Study
PS04-3215	Expert Consensus on Decision-Making Factors for Continuation of Esketamine Nasal Spray in Treatment-Resistant Depression: A Delphi Method
PS02-1216	ECHO: Study Design and Baseline Characteristics of a Non-Interventional Cohort Study of Esketamine Nasal Spray in Treatment-Resistant Depression
PS02-1219	Patient Characteristics Associated With Relative Benefit of Esketamine Nasal Spray Versus Quetiapine Extended Release on Achieving Remission in ESCAPE-TRD Study
PS02-1111	Evolution of Clinical Dimensions and Safety in Patients With Major Depressive Disorder Treated by Esketamine: The French Real-World ELLIPSE Study
PS01-0076	Prevalence, Incidence, and Therapy of (Treatment-Resistant) Depression in Germany: A Sickness Funds Analysis
Schizophrenia	
PS01-0220	Impact of Paliperidone Palmitate 1-Month and 3-Month Long-Acting Injectables on Clinical and

	Psychosocial Outcomes in Rwandan Patients With Schizophrenia
PS04-3104	Lumateperone For The Prevention of Relapse in Patients with Schizophrenia: Results From a Double-Blind, Placebo-Controlled, Randomized Withdrawal, Phase 3 Trial

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.[8,9] In 2023, approximately 22 million adults in the U.S. had at least one major depressive episode.[10] 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.[1,2] As a result, responses to treatment vary widely. With current standard-of-care oral antidepressants, 2 in 3 people living with MDD continue to experience residual or persistent symptoms.[11] 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.[12]

Insomnia is one of the most common symptoms of MDD, affecting more than 80 percent of people living with MDD.[13] 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.[14,15]

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.[16,17] TRD has a significant negative impact on the lives of those affected and has one of the highest economic burdens of all psychiatric disorders.[17] Patients often cycle through multiple oral medications, waiting 4-6 weeks for potential relief.[18] Based on the STAR*d study, after trying their third oral antidepressant, approximately 86 percent of patients do not achieve remission.[18]

ABOUT CAPLYTA®

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

While its exact mechanism of action is unknown, CAPLYTA® is characterized by high serotonin 5-HT_{2A} receptor occupancy and lower amounts of dopamine D^2 receptor occupancy at therapeutic doses.

A supplemental new drug application (sNDA) for CAPLYTA® as an adjunctive treatment for adults with major depressive disorder is currently under U.S. Food and Drug Administration review.

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 and restoring sleep without next-day sedation in patients with depression.[19] 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.[20,21] Seltorexant is the only investigational therapy being studied in MDD that is believed to work by normalizing the overactivation of the orexin-2 receptors, thereby addressing the underlying biology that contributes to depression and causes 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.

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 U.S. yet remains widely misunderstood and insufficiently treated.[22] Symptoms vary by person, but confusion and distortions in perceptions, emotions, and behavior are common.[23] 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.[24,25] 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.[26]

ABOUT JOHNSON & JOHNSON'S SCHIZOPHRENIA PORTFOLIO

Johnson & Johnson's portfolio of schizophrenia therapies offers the broadest range of oral and long-acting injectable treatment options to support each patient's individual treatment journey. The Company's long-acting injectable treatments for adults with schizophrenia provides the most 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.[23,24]

CAPLYTA® is a once-daily oral therapy approved to treat adults with schizophrenia. A supplemental New Drug Application (sNDA) for CAPLYTA® with long-term data evaluating the safety and efficacy of the medication for the prevention of relapse in schizophrenia was recently **submitted** to the U.S. Food and Drug Administration.

CAPLYTA® IMPORTANT SAFETY INFORMATION

CAPLYTA® (lumateperone) is indicated in adults for the treatment of schizophrenia and depressive episodes associated with bipolar I or II disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate.

Important Safety Information

Boxed Warnings:

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. CAPLYTA is not approved for the treatment of patients with dementia-related psychosis.
- Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adults in short-term studies. All antidepressant-treated patients should be closely monitored for clinical worsening, and for emergence of suicidal thoughts and behaviors. The safety and effectiveness of CAPLYTA have not been established in pediatric patients.

Contraindications: CAPLYTA is contraindicated in patients with known hypersensitivity to lumateperone or any components of CAPLYTA. Reactions have included pruritus, rash (e.g., allergic dermatitis, papular rash, and generalized rash), and urticaria.

Warnings & Precautions: Antipsychotic drugs have been reported to cause:

- Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis, including stroke and transient ischemic attack. See Boxed Warning above.
- Neuroleptic Malignant Syndrome (NMS), which is a potentially fatal reaction. Signs and symptoms include: high fever, stiff muscles, confusion, changes in breathing, heart rate, and blood pressure, elevated creatinine phosphokinase, myoglobinuria (and/or rhabdomyolysis), and acute renal failure. Patients who experience signs and symptoms of NMS should immediately contact their doctor or go to the emergency room.
- Tardive Dyskinesia, a syndrome of uncontrolled body movements in the face, tongue, or other body parts, which may increase with duration of treatment and total cumulative dose. TD may not go away, even if CAPLYTA is discontinued. It can also occur after CAPLYTA is discontinued.
- Metabolic Changes, including hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. Hyperglycemia,

in some cases extreme and associated with ketoacidosis, hyperosmolar coma or death, has been reported in patients treated with antipsychotics. Measure weight and assess fasting plasma glucose and lipids when initiating CAPLYTA and monitor periodically during long-term treatment.

- Leukopenia, Neutropenia, and Agranulocytosis (including fatal cases). Complete blood counts should be performed in patients with pre-existing low white blood cell count (WBC) or history of leukopenia or neutropenia. CAPLYTA should be discontinued if clinically significant decline in WBC occurs in absence of other causative factors.
- Decreased Blood Pressure & Dizziness. Patients may feel lightheaded, dizzy or faint when they rise too quickly from a sitting or lying position (orthostatic hypotension). Heart rate and blood pressure should be monitored and patients should be warned with known cardiovascular or cerebrovascular disease. Orthostatic vital signs should be monitored in patients who are vulnerable to hypotension.
- Falls. CAPLYTA may cause sleepiness or dizziness and can slow thinking and motor skills, which may lead to falls and, consequently, fractures and other injuries. Patients should be assessed for risk when using CAPLYTA.
- Seizures. CAPLYTA should be used cautiously in patients with a history of seizures or with conditions that lower seizure threshold.
- Potential for Cognitive and Motor Impairment. Patients should use caution when operating machinery or motor vehicles until they know how CAPLYTA affects them.
- Body Temperature Dysregulation. CAPLYTA should be used with caution in patients who may experience conditions that may increase core body temperature such as strenuous exercise, extreme heat, dehydration, or concomitant anticholinergics.
- Dysphagia. CAPLYTA should be used with caution in patients at risk for aspiration.

Drug Interactions: CAPLYTA should not be used with CYP3A4 inducers. Dose reduction is recommended for concomitant use with strong CYP3A4 inhibitors or moderate CYP3A4 inhibitors.

Special Populations: Newborn infants exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. Dose reduction is recommended for patients with moderate or severe hepatic impairment.

Adverse Reactions: The most common adverse reactions in clinical trials with CAPLYTA vs. placebo were somnolence/sedation, dizziness, nausea, and dry mouth.

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

Please click here to see full Prescribing Information including Boxed Warnings.

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.

cp-170363v4

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.

INVEGA SUSTENNA®, INVEGA TRINZA®, INVEGA HAFYERA® 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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https://www.intracellulartherapies.com/docs/caplyta_pi.pdf

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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 CAPLYTA®, Seltorexant, SPRAVATO®, INVEGA HAFYERA®, INVEGA TRINZA® and INVEGA SUSTENNA®. 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 healthcare products and services; changes to applicable laws and regulations, including global healthcare reforms; and trends toward healthcare 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 U.S. 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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