Johnson&Johnson

NEWS RELEASE

Johnson & Johnson highlights innovative neuropsychiatry portfolio and pipeline at Psych Congress

2024-10-24

- New five-year data reinforce long-term safety and efficacy of SPRAVATO® (esketamine) in patients with inadequate response to two or more oral antidepressants (treatment-resistant depression)
- 23 abstracts highlight data from Company's robust portfolio and pipeline, including clinical insights on major depressive disorder and the significant burden of anhedonia and insomnia symptoms
- Large real-world analysis highlights the link between reducing relapse and improving survival in schizophrenia

TITUSVILLE, N.J., Oct. 24, 2024 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) announced today that 23 abstracts featuring new real-world and clinical trial data from across its neuropsychiatry portfolio and pipeline will be presented at the annual U.S. Psychiatric and Mental Health Congress (Psych Congress), taking place October 29 to November 2 in Boston, Massachusetts. Presentations include new data supporting the safety and efficacy of SPRAVATO® (esketamine) CIII nasal spray and the Company's innovative portfolio of long-acting injectables (LAIs) for schizophrenia, as well as data highlighting the significant burden people living with major depressive disorder (MDD) and schizophrenia often face.

"For nearly seven decades, J&J has been at the forefront of driving scientific progress and innovation in neuroscience," said Bill Martin, Ph.D., Global Neuroscience Therapeutic Area Head, Johnson & Johnson Innovative Medicine. "It is our responsibility and privilege to help advance research and understanding of MDD and schizophrenia so we can continue to deliver transformational therapies that address the greatest unmet patient needs."

Key presentations include:

- New five-year, real-world safety data from nearly 35,000 adults treated with SPRAVATO®, building on more than a decade of research and reinforcing its well-studied, consistent safety profile (Poster 151).
- Novel insights into the clinical, humanistic and economic burden of anhedonia in adults with MDD (Poster 113).
- Results from an analysis of more than 30,000 adults with schizophrenia highlighting the link between symptom relapse and risk of death, which can occur 15-20 years prematurely for adults living with schizophrenia compared to the general population due to many different causes.[1] (Poster 42).

"Serious mental illness is one of the most complex health challenges of our time," said Pearl Pugh, President, U.S. Neuroscience, Johnson & Johnson Innovative Medicine. "Understanding the patient experience is at the core of our mission to develop breakthrough solutions that can help improve care and make a difference in the lives of those living with challenging-to-treat mental illnesses."

J&J will present the following posters at Psych Congress on October 31 from 1:30-3:30 p.m. ET and November 1 from 1:30-3:30 p.m. ET in the Exhibit Hall.

Poster #	Title
Treatment-Resistant Depression	
151	Real-World Safety Profile of Esketamine Nasal Spray: An Analysis of the Risk Evaluation and Mitigation Strategy Program Approximately 5 Years After Approval in the United States
112	Efficacy and Safety of Esketamine Nasal Spray as Monotherapy in Adults with Treatment-Resistant Depression: A Randomized, Double-Blind, Placebo-Controlled Study
102	Weight and Metabolic Changes in Patients Treated with Esketamine Nasal Spray Versus Quetiapine Extended Release: A Post Hoc Subgroup Analysis of the ESCAPE-TRD Study
200	Clinical Effectiveness and Persistence on Esketamine Nasal Spray in Patients with Treatment-Resistant Depression Overall and Among Transcranial Magnetic Stimulation-Naïve Subgroup
202	Response and Remission on Esketamine Nasal Spray in Patients with Treatment-Resistant Depression Overall and Among TMS-Naive Subgroup
203	Comparison of Real-World Response and Remission Among Patients with Treatment-Resistant Depression Treated with Esketamine Nasal Spray or Antipsychotic Augmentation
201	Real-World Clinical Effectiveness of Esketamine Nasal Spray Based on the Montgomery-Åsberg Depression Rating Scale (MADRS) Among Patients with Treatment-Resistant Depression in the United States
148	Trajectory of Response and Remission in Induction Nonresponders to Esketamine Nasal Spray: A Subgroup Analysis of the SUSTAIN-3 Study
Major Depressive Disorder	
113	Higher Anhedonia Is Associated with Poorer Clinical and Humanistic Outcomes Among U.S. Adults with Major Depressive Disorder
124	Seltorexant, Adjunctive to Antidepressants, in Adults with Major Depressive Disorder with Insomnia Symptoms: Results of a Double-Blind, Randomized, Placebo-Controlled Study
206	Adjunctive Treatment with Seltorexant Improved Patient-Reported Depressive Symptoms, Insomnia Symptoms, and Overall Health in Major Depressive Disorder with Insomnia
59	Pharmacokinetics and Safety of Seltorexant, Selective Orexin-2 Receptor Antagonist, in Healthy Elderly and Young Non-Asian, and Japanese Adult Participants
145	Major Depressive Disorder with Clinically Relevant Insomnia Symptoms: Healthcare Professional Assessment of Patient Impact and Clinical Management
146	Treating Insomnia Symptoms as Part of Major Depressive Disorder: A Cross-Sectional Survey on Patient Needs in the U.S.
186	How Do Patients with Depression and Their Providers Talk About Anhedonia? An Ethnographic Analysis of Healthcare Provider Conversations with Patients in the Clinical Setting
16	Burden of Prominent Anhedonia in Major Depressive Disorder Reflected in Polypharmacy, Healthcare Use, and Humanistic Outcomes
64	Clinical Burden and Treatment Satisfaction in a Real-World Survey of Patients Diagnosed with Major Depressive Disorder (MDD) With Prominent Anhedonia
147	Disease Burden Associated with Prominent Anhedonia in Patients with Major Depressive Disorder (MDD) from Adelphi Depression Disease Specific Program
32	Clinical Burden of Patients Diagnosed with Major Depressive Disorder with versus Without Prominent Anhedonia Using a Real-World Dataset in the United States
Schizophrenia	
42	Association of Relapse with All-Cause Mortality in 32,071 Adults with Stable Schizophrenia: A Longitudinal Commercial and Medicare

	Database Study
39	Characteristics and Antipsychotic Treatment Pathways of Patients with Schizophrenia Who Received Once-Every-6-Months Paliperidone Palmitate Within the First Two Years of Approval
34	Real-World Comparative Effectiveness of Long-Acting Injectable and Oral Antipsychotics Among U.S. Medicare Beneficiaries with Schizophrenia
103	Symptomatic and Functional Remission with Paliperidone Palmitate 3-Month and 6-Month Formulations in Adult Patients with Schizophrenia: A 3-Year Analysis

ABOUT TREATMENT-RESISTANT DEPRESSION

Depression is a common mental health disorder that impacts an estimated 280 million people worldwide.[2] In the U.S., approximately 21 million adults have had at least one major depressive episode, and approximately one-third of medication-treated adults are considered to have TRD.[3,4] People living with MDD are often considered to have TRD if they have not responded adequately to at least two different antidepressants of adequate dose and duration in the current depressive episode.[4] TRD has a significant negative impact on the lives of those affected and has one of the highest economic burdens of all psychiatric disorders.[4]

ABOUT SPRAVATO®

SPRAVATO® (esketamine) CIII nasal spray is approved by the U.S. Food and Drug Administration in combination with an oral antidepressant for adults with TRD and depressive symptoms in adults with major depressive disorder with acute suicidal ideation or behavior. It is the first treatment to use a new mechanism of action in decades for the treatment of TRD. SPRAVATO® is a non-selective, non-competitive antagonist of the N-methyl-D-aspartate (NMDA) receptor and is believed to work differently by acting on a pathway in the brain that affects glutamate. To date, SPRAVATO® has been approved in 79 countries and administered to more than 100,000 patients worldwide.

ABOUT MAJOR DEPRESSIVE DISORDER WITH INSOMNIA SYMPTOMS

MDD is one of the most common psychiatric disorders and leading causes of disability worldwide,[5] with an estimated 280 million people living with the disorder around the world.[2] MDD is often accompanied by sleep disturbances such as insomnia or hypersomnia, affecting up to 60 percent of patients with MDD.[6] 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.[7,8]

ABOUT SELTOREXANT

Seltorexant, an investigational potential 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 is believed to selectively antagonize the orexin-2 receptors, potentially improving mood and sleep symptoms associated with depression. 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.

ABOUT SCHIZOPHRENIA

Schizophrenia is a chronic and severe brain disorder affecting approximately 20 million people worldwide and an estimated 2.4 million adults in the U.S.[9-11] The disease is characterized by distortions in thinking, perception, emotions, language, sense of self, and behavior.[9] It can also lead to neurological impairment and severe disability.[12] Antipsychotic medication is recognized as an essential component in the treatment of schizophrenia, and adherence to medication plays a critical role in controlling symptoms and costly relapses.[13]

ABOUT J&J'S U.S. LONG-ACTING INJECTABLES

The J&J U.S. portfolio of 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. Our portfolio includes 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.

Long-acting injectables (LAIs) allow for the slow release of medicine into the bloodstream and have been available and studied for more than 50 years. Based on clinical guidance, the National Council for Mental Wellbeing and the American Psychiatric Association have updated their guidance and practice guidelines to recommend the use of LAIs for appropriate patients.[14-16]

SPRAVATO® IMPORTANT SAFETY INFORMATION

What is SPRAVATO® (esketamine) CIII nasal spray?

SPRAVATO® is a prescription medicine, used along with an antidepressant taken by mouth to treat:

- Adults with treatment-resistant depression (TRD)
- 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 and dissociation. SPRAVATO® may cause sleepiness (sedation), fainting, dizziness, spinning sensation, anxiety, or feeling disconnected from yourself, your thoughts, feelings, space and time (dissociation).
  - 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.
- Respiratory depression was observed with the use of SPRAVATO®; additionally, there were rare reports of respiratory arrest.
  - Your healthcare provider must monitor you for serious side effects for at least 2 hours (including pulse oximetry) 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 physical and psychological dependence with SPRAVATO® treatment. Your healthcare provider should check you for signs of abuse and dependence before and during treatment with SPRAVATO®.
  - 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 (e.g., 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.
  - 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 right away if you or your family member have any of the following symptoms, especially if they are new, worse, or worry you:
  - suicide attempts
  - thoughts about suicide or dying
  - worsening depression
  - 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 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. 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) medicine. 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 when used along with an antidepressant taken by mouth 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
- 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 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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INVEGA® 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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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 where 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 **http://www.jnj.com** or at **www.innovativemedicine.jnj.com**.

Follow us at @JanssenUS and @JNJInnovMed.

Janssen Research & Development, LLC and Janssen Biotech, Inc. are Johnson & Johnson companies.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits and treatment impact of nipocalimab. 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 Janssen Research & Development, LLC, Janssen Biotech, Inc. and/or 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2023, 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** or on request from Johnson & Johnson. None of Janssen Research & Development, LLC, Janssen Biotech, Inc. nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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