News Release

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Janssen to Showcase New Insights and Commitment to Accelerating Hope and Healing for Serious Mental Illness at Psych Congress 2023

Key analyses examine long-term safety and efficacy of medicines for treatment-resistant depression and schizophrenia

Titusville, New Jersey, September 5, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson will showcase data from its neuropsychiatry portfolio at Psych Congress 2023. The Company will present 15 posters, including clinical and real-world data, reinforcing its commitment to furthering innovation and research that give hope to patients living with serious mental illness, including treatment-resistant depression (TRD), schizophrenia and major depressive disorder (MDD).

"Janssen Neuroscience is investing in research to understand how our medicines are benefitting patients long-term, demonstrating our duty and commitment to healing minds and restoring hope for depression and schizophrenia disorders within the serious mental illness community," said Reina Benabou, M.D., Ph.D., Vice President, Medical Affairs, Neuroscience, Janssen Scientific Affairs, LLC. "The data presented at Psych Congress show the value and promise of our current and future treatments and bring to life the real long-term difference these treatments can make for patients in managing their mental health conditions."

Data from individual studies will be featured in several posters exploring the long-term impact of SPRAVATO® (esketamine) CIII nasal spray for adults with TRD and INVEGA HAFYERA® (6-month paliperidone palmitate) for adults with schizophrenia.

Key highlights include:

Treatment-resistant depression

- Final results and two additional analyses from the SUSTAIN-3 open-label, long-term extension trial, assessing the long-term safety and efficacy of SPRAVATO® in treating adults with TRD up to 6.5 years. (64, 77, 78)
- Real-world safety data from the Risk Evaluation and Mitigation Strategy (REMS) program of nearly 35,000 patients taking SPRAVATO® over the first four years. (79)
- A sub-group analysis of the ESCAPE-TRD trial assessing work productivity and related costs among adults with TRD treated with SPRAVATO® consistent with the U.S. prescribing label compared to quetiapine extended-release, both used in conjunction with an oral antidepressant. (117)

Schizophrenia

- An analysis assessing the safety and efficacy of INVEGA HAFYERA® for up to 3 years; this study followed clinically stable adult patients with schizophrenia from a double-blind randomized controlled trial through a two-year single-arm, open-label extension study. (87)

Pipeline

- A double-blind, active- and placebo-controlled, dose-finding study evaluating seltorexant for clinical improvements in adults and elderly patients with insomnia disorder. (66)
- Two analyses of real-world, patient-reported outcomes evaluating the prevalence of anhedonia (loss of ability to feel pleasure) and its impact on health-related outcomes for adults with MDD. (19, 47)

"At Janssen Neuroscience, we're using our groundbreaking science and expertise to develop a promising pipeline to address unmet needs for people living with mental health conditions," said Bill Martin, Ph.D., Global Therapeutic Area Head, Neuroscience, Janssen Research and Development, LLC. "We are prioritizing data-driven therapeutic discovery, validation and clinical translation strategies in our disease areas of focus to work towards a future where people living with challenging-to-treat mental illness have the options they need to manage their conditions."

Janssen Neuroscience will present these posters on September 8 and 9 from 1:30-3 pm CT in Exhibit Hall A and B.

Poster #	Title
Treatment-Resistant Depression	
64	Long-term Safety of Esketamine Nasal Spray Dosed in Accordance with U.S. Prescribing Information in Adults With Treatment-Resistant Depression: A Subgroup Analysis of the SUSTAIN-3 Study Up to 6.5 Years
77	Long-Term Efficacy of Esketamine Nasal Spray Dosed in Accordance With U.S. Prescribing Information in Adults With Treatment-Resistant Depression: A Subgroup Analysis of the SUSTAIN-3 Study Up to 6.5 Years

78	Long-Term Safety and Maintenance of Response with Esketamine Nasal Spray in Treatment-Resistant Depression: Final Results of the SUSTAIN-3 Study
79	Real-World Safety Profile of Esketamine Nasal Spray During the First 12 Treatment Sessions: An Analysis at 46 Months After Approval in the United States
117	Costs Associated with Work Productivity Loss of Patients with Treatment-Resistant Depression Treated with Esketamine Nasal Spray Versus Quetiapine Extended Release: ESCAPE-TRD Subgroup Analysis
81	Time Dynamics of Adverse Events of Interest Occurring With Esketamine Nasal Spray and Quetiapine Extended Release: Results from the ESCAPE-TRD Phase 3b Trial
80	Esketamine Nasal Spray Improves Functioning in Patients with Treatment-Resistant Depression: Results From ESCAPE-TRD, A Randomized Phase 3b Trial
119	Understanding Profiles of Patients with Treatment-Resistant Depression by Stringency of Health Plan Prior Authorization Criteria for Approval of Esketamine
118	Understanding Patient Profiles Among Medicaid Patients With Treatment-Resistant Depression Initiated on Esketamine
Schizophrenia	
87	Efficacy and Safety of Paliperidone Palmitate 6-Month Formulation: A 3-Year Analysis in Adults With Schizophrenia
116	Efficacy and Safety Outcomes When Transitioning to Paliperidone Palmitate 6-Month from Paliperidone Palmitate 1-Month Versus Paliperidone Palmitate 3-Month
61	Relapse Rates with Paliperidone Palmitate in Adult Patients with Schizophrenia: Results for the 6-Month Formulation from an Open-Label Extension Study Compared to Real-World Data for the 1-Month and 3-Month Formulations
Major Depressive Disorder Pipeline	
66	Efficacy and Safety of Seltorexant in Insomnia Disorder
19	Association between Anhedonia Severity and Clinical and Humanistic Outcomes Among U.S. Adults with Major Depressive Disorder
47	Qualitative Study to Assess the Patient Perspective on Anhedonia Symptoms and Impacts in Major Depressive Disorder

About SPRAVATO®

SPRAVATO® (esketamine) CIII nasal spray is a non-selective, non-competitive antagonist of the N-methyl-D-aspartate (NMDA) receptor – an ionotropic glutamate receptor. It has a novel mechanism of action, meaning it works differently than currently available therapies for major depressive disorder (MDD), and is the first new mechanism of action for MDD in decades.

SPRAVATO® is approved in the United States, in conjunction with an oral antidepressant, to treat adults with treatment-resistant depression (TRD) and depressive symptoms in adults with MDD with acute suicidal ideation or behavior.

About Treatment-Resistant Depression

Depression is a common mental disorder that impacts an estimated 280 million people worldwide.[1] In the U.S., approximately 21 million adults have had at least one major depressive episode, with an estimated one-third—or 2.8 million—of those living with MDD

diagnosed with TRD.[2,3] TRD places an ongoing emotional, functional and economic burden on the individual, their loved ones and society.[2] TRD has a significant negative impact on the lives of those affected and has one of the highest economic burdens of all psychiatric disorders.[2] 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.[2]

About INVEGA HAFYERA®

INVEGA HAFYERA® (6-month paliperidone palmitate) is a long-acting injectable treatment that is administered by a healthcare provider in the upper buttocks area every six months after being adequately treated with either INVEGA SUSTENNA® (1-month paliperidone palmitate) or INVEGA TRINZA® (3-month paliperidone palmitate). INVEGA HAFYERA® dissolves slowly into the bloodstream after injection, resulting in continuous treatment and symptom control over six months.

The Janssen 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 available. Our portfolio includes INVEGA SUSTENNA®, INVEGA TRINZA®, and INVEGA HAFYERA®, 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.[4] 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.[5-7]

About Schizophrenia

Schizophrenia is a chronic and severe brain disorder affecting approximately 20 million people worldwide and an estimated 2.8 million adults in the U.S.[8-10] The disease is characterized by distortions in thinking, perception, emotions, language, sense of self, and behavior.[8] It can also lead to neurological impairment and severe disability.[11] 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.[12]

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.

- **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, 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) 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® 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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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 the Janssen Pharmaceutical Companies of Johnson & Johnson
At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular, Metabolism & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension. Learn more at www.janssen.com. Follow us at @JanssenGlobal and @JanssenUS. Janssen Research & Development, LLC and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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 SPRAVATO® (esketamine) and INVEGA-HAFYERA® (6-month paliperidone palmitate). 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 and Development, LLC, Janssen Biotech, Inc., any of the other Janssen Pharmaceutical Companies 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; competition, including technological advances, new products and patents attained by competitors; challenges to patents; 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 January 1, 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 and Development, LLC, Janssen Biotech, Inc., the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

For more information about INVEGA HAFYERA® visit invegahafyerahcp.com, and for more information about SPRAVATO®, visit spravatohcp.com.

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