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LANDMARK SCHIZOPHRENIA DATA THAT BRING HOPE IN BREAKING THE CYCLE OF HOSPITALIZATION AND INCARCERATION RECEIVE FDA APPROVAL FOR INCLUSION IN INVEGA SUSTENNA® (paliperidone palmitate) LABEL

INVEGA SUSTENNA® is the first and only antipsychotic to demonstrate superior effectiveness in delaying time to relapse versus a group of seven commonly prescribed oral antipsychotics in adults with schizophrenia who face common real-world circumstances

TITUSVILLE, N.J., January 3, 2018 – Janssen Pharmaceuticals, Inc., today announced INVEGA SUSTENNA® (paliperidone palmitate), a once-monthly schizophrenia treatment, is the first and only antipsychotic to have the U.S. Food and Drug Administration (FDA) approve the inclusion of real-world data in its product labeling. These data come from the **P**aliperidone Palmitate **R**esearch **I**n **D**emonstrating **E**ffectiveness (PRIDE) study and demonstrate:

- The superior effectiveness of INVEGA SUSTENNA® versus a group of seven commonly prescribed oral antipsychotics in delaying time to relapse, and
- The time to first psychiatric hospitalization or arrest and/or incarceration was significantly longer for people treated with INVEGA SUSTENNA® versus these same commonly prescribed oral antipsychotics.

Click to Tweet: Landmark data that bring hope in breaking the cycle of hospitalization and incarceration associated with #schizophrenia approved by @US_FDA for inclusion in antipsychotic treatment label http://po.st/MUWq5V

"This important study helped us better understand the effectiveness of antipsychotic treatments when used outside the controlled setting of a typical clinical trial, where difficult circumstances like hospitalization, incarceration and substance abuse are an unfortunate reality for individuals living with schizophrenia," explained trial investigator Martha Sajatovic, MD, Director, Neurological and Behavioral Outcomes Center, University Hospitals Cleveland Medical Center. "Healthcare providers often treat schizophrenia with oral medications and do not offer the option of long-acting therapy until later in the treatment journey, when the disease has advanced. Based on the addition of this comparative evidence to the Invega Sustenna label, healthcare professionals should consider the benefits of earlier treatment with a long-acting therapy in their adult patients living with schizophrenia."

This study has the potential to address key issues impacting the broader healthcare system. Today, the criminal justice system is the largest provider of mental health care in the United States, in part due to variable access to care. People in this country living with serious mental illness (SMI), including those with schizophrenia, are three times more likely to be in

jail or prison than a hospital, often as a result of their symptoms. Despite widespread use of antipsychotics, sometimes people have difficultly taking daily medication as prescribed, increasing the risk of their symptoms returning. These repeated cycles of relapse lead to costly events, such as hospitalization or incarceration.

"When a treatment fails and a person living with schizophrenia relapses, it's not only extraordinarily discouraging and difficult for the individual and their family, it can also be burdensome and costly for our healthcare system," said Michelle Kramer, MD, MPH, Vice President, Neuroscience Medical Affairs, Janssen. "The inclusion of this novel evidence in the Invega Sustenna label will help adults living with schizophrenia and their healthcare providers see what's possible with the right treatment plan and support."

Click to Tweet: Hear from Tanara, a person living with #schizophrenia who overcame incarceration with the right treatment plan, by clicking here: http://po.st/1qHsAy

PRIDE Trial

The label update is based on data from the groundbreaking PRIDE study and reflects the clinical and real-world benefits of INVEGA SUSTENNA® (paliperidone palmitate). The comparative efficacy PRIDE trial was a 15-month, multi-center, prospective, randomized, open-label, active-controlled study of 444 adults with schizophrenia. Participants were enrolled at 50 sites across the United States and Puerto Rico.

The trial was uniquely designed to mirror the population of adults living with schizophrenia that healthcare professionals commonly see in clinical practice. All trial participants were adults who had been diagnosed with schizophrenia and taken into custody by the criminal justice system at least twice in the previous two years, with at least one custody resulting in incarceration. This trial allowed participation by those often excluded from trials, such as individuals with a recent history of incarceration, as well as those who had self-reported substance or alcohol abuse just prior to trial enrollment or who had a current diagnosis of a substance abuse disorder. Patients who had abused intravenous drugs within three months of screening or had an opiate dependence disorder were not included in the trial.

The PRIDE study was originally published online in *The Journal of Clinical Psychiatry* on April 14, 2015.

In the PRIDE study, participants were randomized to either monthly INVEGA SUSTENNA® or one of seven commonly prescribed daily antipsychotic therapies used in the United States: aripiprazole, haloperidol, olanzapine, paliperidone, perphenazine, quetiapine and risperidone. Clinicians were permitted to determine the appropriate oral antipsychotic based on a patient's prior experience, as is typical in the real world. The study was not powered to compare the efficacy of INVEGA SUSTENNA® with that of the individual commonly prescribed oral antipsychotics used in the study.

The primary study endpoint was median length of time to the first treatment failure or relapse. The results found that INVEGA SUSTENNA® delivered a statistically significant delay in relapse, more than six months longer than a group of seven commonly prescribed oral antipsychotics (median 416 days versus median 226 days; P=0.011). The time to first

psychiatric hospitalization or arrest and/or incarceration was also significantly longer for the INVEGA SUSTENNA® group versus the oral antipsychotic group.

In this study, treatment failure was defined as psychiatric hospitalization; arrest/incarceration; suicide; treatment supplementation/discontinuation of antipsychotic treatment because of inadequate efficacy, safety, or tolerability; or need for increased psychiatric services to prevent imminent psychiatric hospitalization.

No new safety issues were observed during the study. The most common INVEGA SUSTENNA® adverse reactions during placebo-controlled studies (≥5% and twice placebo) were injection site reactions, somnolence/sedation, dizziness, akathisia, and extrapyramidal disorder. During the PRIDE study, the most common adverse reactions (≥5% and twice oral antipsychotic group) were injection site pain, weight increased, fatigue, erectile dysfunction and libido decreased.

About Schizophrenia
Schizophrenia is a complex and chronic brain disorder that can be severe and disabling. It affects approximately 2.4 million U.S. adults,[1] often beginning in the late teens or early twenties. The disease typically manifests as hallucinations, delusions and disorganized thoughts and behavior.

About INVEGA SUSTENNA®
INVEGA SUSTENNA® (paliperidone palmitate) was approved by the U.S. FDA in July 2009 as the first once-monthly, atypical, long-acting injection to treat schizophrenia and is now approved in more than 80 countries. In November 2014, the FDA approved INVEGA SUSTENNA® for the treatment of schizoaffective disorder, making it the first and only once-monthly medication to treat this condition; however, people living with schizoaffective disorder were not studied as part of the PRIDE trial.

About Janssen Pharmaceuticals, Inc.
At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenUS.

Janssen Pharmaceuticals, Inc., is part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Janssen Pharmaceuticals, Inc., markets INVEGA SUSTENNA® in the United States.

INDICATIONS
INVEGA SUSTENNA® (In-VEY-guh Suss-TEN-uh) (paliperidone palmitate) Extended-Release Injectable Suspension is a prescription medicine given by injection by a healthcare professional. INVEGA SUSTENNA® is used to treat schizophrenia.

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

INVEGA SUSTENNA® can cause serious side effects, including an increased risk of death in elderly people who are confused, have memory loss, and have lost touch with reality (dementia-related psychosis). INVEGA SUSTENNA® is not for treating dementia-related psychosis.

Do not receive INVEGA SUSTENNA® if you are allergic to paliperidone, paliperidone palmitate, risperidone, or any of the ingredients in INVEGA SUSTENNA®. See the end of the Patient Information leaflet in the full Prescribing Information for a complete list of INVEGA SUSTENNA® ingredients.

Before you receive INVEGA SUSTENNA®, tell your healthcare provider 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 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 SUSTENNA® will harm your unborn baby
    - infants born to women who are treated with INVEGA SUSTENNA® may have withdrawal symptoms or other symptoms such as tremors, muscle spasms, abnormal movement of arms and legs, and twitching of eyes.
- are breastfeeding or plan to breastfeed. INVEGA SUSTENNA® can pass into your breast milk and may harm your baby. You and your healthcare provider should decide if you will receive INVEGA SUSTENNA® or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show to your healthcare provider 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 provider for the potential risk of falls.

What should I avoid while receiving INVEGA SUSTENNA®?

- 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 SUSTENNA® affects you
- avoid getting overheated or dehydrated

INVEGA SUSTENNA® may cause serious side effects, including:

- **See "What is the most important information I should know about 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 SUSTENNA®. NMS can cause death and must be treated in a hospital. Call your healthcare provider 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 provider 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 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 provider 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 SUSTENNA® include: injection site reactions; sleepiness or drowsiness; dizziness; feeling 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 provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of INVEGA SUSTENNA®. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

General information about the safe and effective use of INVEGA SUSTENNA®.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use INVEGA SUSTENNA® for a condition for which it was not prescribed. Do not give INVEGA SUSTENNA® to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about INVEGA SUSTENNA® that is written for healthcare professionals.

This Patient Information leaflet summarizes the most important information about INVEGA SUSTENNA®. If you would like more information, talk with your healthcare provider.

You can ask your healthcare provider or pharmacist for more information that is written for healthcare professionals. For more information, go to www.invegasustenna.com or call 1-800-526-7736.

Please see full Prescribing Information including Boxed WARNING for INVEGA SUSTENNA® (paliperidone palmitate) and INVEGA® (paliperidone) at http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/INVEGA+SUSTENNA-pi.pdf and www.JanssenCNS.com/Invega.

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding continued development of INVEGA SUSTENNA® (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 Pharmaceuticals, Inc., any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in product development, including obtaining regulatory approvals; uncertainty of commercial impact, if any, of label updates; 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 to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and description 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, 2017, including under "Item 1A. Risk Factors," its most recently filed Quarterly Report on Form 10-Q, including under the caption "Cautionary Note Regarding Forward-Looking Statements," and the company's subsequent 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. Neither 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.

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[1] National Institutes of Health. NIMH Schizophrenia Fact Sheet. Updated 2010. Available online: https://report.nih.gov/nihfactsheets/Pdfs/Schizophrenia(NIMH).pdf. Accessed December 15, 2017.