NEWS RELEASE

INVEGA TRINZA™, First and Only Four-Times-A-Year Treatment for Schizophrenia, Now Commercially Available

6/25/2015

TITUSVILLE, N.J., June 25, 2015 - The first schizophrenia treatment to be taken just four times a year - with dosing measured in seasons, not days - is now available in the United States. The three-month dosing interval of INVEGA TRINZA™ (paliperidone palmitate) offers a new paradigm for treating patients with schizophrenia. With this newly available treatment option, healthcare providers can give patients greater independence by enabling them to focus less on taking their medication and more on other aspects of their treatment plan.

INVEGA TRINZA™, an atypical antipsychotic injection, is administered just four times a year, providing the longest dosing interval available for people living with schizophrenia. Before starting INVEGA TRINZA™, patients must be adequately treated with INVEGA SUSTENNA® (one-month paliperidone palmitate) for at least four months.

Janssen Pharmaceuticals, Inc. announced that the U.S. Food and Drug Administration (FDA) **recently approved** INVEGA TRINZA™ under Priority Review. This designation is for drugs that, if approved, would offer significant improvement in the treatment of serious conditions.

"With the sustained symptom control offered by INVEGA TRINZA™, my patients and I can focus conversations on more than medication," said clinical trial investigator Joseph Kwentus, MD, Precise Research Centers. "We can start looking at patients' long-term personal goals beyond short-term symptom needs."

The course of schizophrenia is varied, frequently involving periodic relapses of the disease. Each relapse can result in reduced response to treatment, putting continued symptom control even further out of reach. In the Phase 3 clinical trial, 93 percent of patients treated with INVEGA TRINZA™ remained relapse-free and did not experience a

significant return of schizophrenia symptoms in a long-term maintenance trial. The **results** of this study were published in March by JAMA Psychiatry, a peer-reviewed medical journal published by the American Medical Association. Based on positive efficacy, Janssen concluded this study early following the recommendation of an Independent Data Monitoring Committee (IDMC).

"Treatment for schizophrenia is believed to be more effective if it is begun early in the course of the illness," said Tarry Wolfe, DNP, FNP-c, PMHNP-BC, Community Bridges, Inc. "The medical community needs a broad range of treatments to help individuals living with schizophrenia, and INVEGA TRINZA™ is now another medication option."

Over the years, Janssen has remained committed to meeting patients' needs related to their treatment. Janssen Pharmaceuticals, Inc. developed and launched **JANSSEN CONNECT®**, an information and assistance program designed to help patients start and stay on their Janssen long-acting injectable atypical antipsychotic after their healthcare professional has deemed it to be the most clinically appropriate treatment option. JANSSEN CONNECT® now provides information and assistance to patients prescribed INVEGA SUSTENNA® and INVEGA TRINZA™, both of which are part of the Janssen family of long-acting injectable atypical antipsychotic medications.

Please visit **www.InvegaTrinzaHCP.com** for more information and unique resources for physicians, nurses and pharmacists, including:

- Dosing and Administration Guide with detailed information on the four-times-a-year dosing regimen, starting patients, addressing missed doses, and more
- Instructions For Use video featuring a step-by-step demonstration of how to prepare and administer a dose of INVEGA TRINZA™
- Patient brochure to help patients and caregivers learn more about the benefits and risks of INVEGA TRINZA™
- Access information including state coverage resources
- Information about JANSSEN CONNECT® and how this program may be able to help patients start and stay on therapy
- Affordability information and available patient discounts

About Schizophrenia

Schizophrenia affects approximately 2.4 million U.S. adults, often beginning in early adulthood, just as individuals are establishing their independence. The course of schizophrenia is varied, frequently involving periodic relapses of the disease with sometimes incomplete response to treatment. Each relapse can result in reduced response to treatment, putting continued symptom control even further out of reach.

About Janssen Pharmaceuticals, Inc.

As a member of the Janssen Pharmaceutical Companies of Johnson & Johnson, Janssen Pharmaceuticals, Inc., is

dedicated to addressing and resolving the major unmet medical needs of our time. Driven by our commitment to patients, healthcare professionals, and caregivers, we strive to develop sustainable and integrated healthcare solutions by working in partnership with all stakeholders on the basis of trust and transparency. Our daily work is guided by meeting goals of excellence in quality, innovation, safety, and efficacy in order to advance patient care.

Our company provides medicines for an array of illnesses and disorders in several therapeutic areas. For more information on Janssen Pharmaceuticals, Inc., visit us at **www.JanssenPharmaceuticalsInc.com** or follow us on Twitter at **www.Twitter.com/JanssenUS** and on YouTube at **www.YouTube.com/JanssenUS**.

About INVEGA TRINZA™

INDICATION

INVEGA TRINZA™ (three-month paliperidone palmitate) is a prescription medicine given by injection every three months by a healthcare professional and used to treat schizophrenia. INVEGA TRINZA™ is used in people who have been treated with INVEGA SUSTENNA® (one-month paliperidone palmitate) for at least four months.

IMPORTANT SAFETY INFORMATION

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

Before you receive INVEGA TRINZA™, 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 TRINZA™ will harm your unborn baby
    - If you become pregnant while taking INVEGA TRINZA™, talk to your healthcare provider 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 TRINZA™ 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 TRINZA™ can pass into your breast milk and may harm your baby. You and your healthcare provider should decide if you will receive INVEGA TRINZA™ 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.

What should I avoid while receiving INVEGA TRINZA™?

- INVEGA TRINZA™ 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 TRINZA™ affects you
- avoid getting overheated or dehydrated

INVEGA TRINZA™ may cause serious side effects, including:

- 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 TRINZA™. 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 TRINZA™ 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

- Call your doctor right away if you start thinking about suicide or wanting to hurt yourself

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.

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 TRINZA™. For more information, ask your healthcare provider or pharmacist.

Call your doctor 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 TRINZA™.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use INVEGA TRINZA™ for a condition for which it was not prescribed. Do not give INVEGA TRINZA™ 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 TRINZA™ that is written for health professionals.

The Patient Information leaflet summarizes the most important information about INVEGA TRINZA™. 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.invegatrinzahcp.com** or call 1 800-526-7736.

About INVEGA SUSTENNA®

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 for schizoaffective disorder either alone or in combination with other medicines such as mood stabilizers or antidepressants and is used to treat schizophrenia.

Do not receive INVEGA SUSTENNA® if you are allergic to paliperidone, risperidone, or any of the ingredients in INVEGA SUSTENNA®. See 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
- 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.

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:

- 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. 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

- Call your doctor right away if you start thinking about suicide or wanting to hurt yourself

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 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.

You are encouraged to report side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch**, or call 1-800-FDA-1088.

Please see full Prescribing Information including Boxed Warning for INVEGA SUSTENNA® (paliperidone palmitate) and INVEGA® (paliperidone) at **www.JanssenCNS.com/InvegaSustenna** and **www.JanssenCNS.com/Invega**.

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