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U.S. FDA Approves INVEGA TRINZA™, First and Only Four-Times-A-Year Treatment for Schizophrenia

93% of patients treated with INVEGA TRINZA™ remained relapse-free at the end of long-term maintenance trial

TITUSVILLE, N.J., May 19, 2015 – There's a new treatment option for schizophrenia – INVEGA TRINZA™ (three-month paliperidone palmitate), the first and only schizophrenia medication to be administered just four times a year, providing the longest dosing interval available.

Janssen Pharmaceuticals, Inc. today announced that the U.S. Food and Drug Administration (FDA) approved under priority review the New Drug Application (NDA) for the three-month long-acting atypical antipsychotic INVEGA TRINZA™. INVEGA TRINZA™, a three-month injection, is an atypical antipsychotic indicated to treat schizophrenia. Before starting INVEGA TRINZA™, patients must be adequately treated with INVEGA SUSTENNA® (one-month paliperidone palmitate) for at least four months. Priority review is a designation for drugs that, if approved, would offer significant improvement in the treatment of serious conditions.

In a long-term maintenance trial, 93 percent of patients treated with INVEGA TRINZA™ did not experience a significant return of schizophrenia symptoms. The results of the phase 3 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).

"With a dosing interval that can be measured in seasons, not days, people living with schizophrenia and their treatment teams can focus on recovery goals beyond short-term symptom control," said trial investigator Joseph Kwentus, MD, Precise Research Centers. "Recovery looks different for everyone, and the long-term symptom control offered by INVEGA TRINZA™ can help patients work toward their own personal goals."

Schizophrenia is a complex and chronic brain disorder in which symptoms can be severe and disabling and can affect all aspects of a person's daily life. With this new 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.

"Building on Janssen's more than 50 years of leadership in developing innovative mental health therapies and helpful programs, this medication offers a new paradigm for treating people living with schizophrenia," said Husseini Manji, MD, Global Head, Neuroscience Therapeutic Area, Janssen Research & Development, LLC. "After at least four months on INVEGA SUSTENNA®, patients and their doctors can seamlessly transition to INVEGA TRINZA™ for sustained symptom control with a single dose every three months."

Janssen anticipates that INVEGA TRINZA™ will be commercially available by mid-June.

"It's encouraging to see continued progress in the treatment of schizophrenia, since access to a range of treatment options is a critical success factor in the treatment journey of individuals living with this disease," said Paul Gionfriddo, president and CEO, Mental Health America. "As both an advocate and a parent of an adult son with schizophrenia, I can attest to the importance of novel therapies that enable our loved ones to spend more time focusing on their recovery and less time worrying about taking medications."

Based on the phase 3 study, the safety and tolerability profile of INVEGA TRINZA™ is consistent with that of INVEGA SUSTENNA®. No new benefit-risk concerns emerged from studies of INVEGA TRINZA™. The safety and tolerability of paliperidone has been established in multiple formulations across many clinical trials. INVEGA TRINZA™ utilizes Alkermes' proprietary NanoCrystal® technology, which enables solubility of poorly water-soluble compounds.

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® supports both INVEGA SUSTENNA® and INVEGA TRINZA™, both of which are part of the Janssen family of long-acting injectable atypical antipsychotic medications.

For more information, please click here.

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™ (3- month paliperidone palmitate) 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 treated with INVEGA SUSTENNA® (1-month paliperidone palmitate) for at least 4 months.

IMPORTANT SAFETY INFORMATION

INVEGA TRINZA™ 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 TRINZA™ is not approved for treating dementia-related psychosis.

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.

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 approved for treating dementia-related psychosis.

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.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding a newly approved product. 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. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: manufacturing difficulties and delays; product efficacy or safety concerns resulting in product recalls or regulatory action; competition, including technological advances, new products and patents attained by competitors; challenges to patents; uncertainty of commercial success; changes in behavior and spending patterns or financial distress 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 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 December 28, 2014, including in Exhibit 99 thereto, 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. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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