



NEWS RELEASE

Janssen Announces 15 Key Research Presentations at Annual Meeting of the American Psychiatric Association

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Janssen Announces 15 Key Research Presentations at Annual Meeting of the American Psychiatric Association TITUSVILLE, N.J., May 12, 2016 /PRNewswire/ -- The Janssen Pharmaceutical Companies announced that several posters related to Janssen's work in mental health will be featured at the 169th Annual Meeting of the American Psychiatric Association in Atlanta, May 14 to 18.

The following posters will be presented at Exhibit Hall B3-B4, Georgia World Congress Center from 2 pm to 4 pm ET:

Monday, May 16

- Healthcare Resource Use in Schizophrenia Patients Treated with Long-Acting Injectable Antipsychotics: Risperidone versus Paliperidone Palmitate
- Medicaid Spending in Schizophrenia Patients Reaching vs. Not Reaching Stabilized Maintenance with Once-Monthly Paliperidone Palmitate
- Outcomes among Stabilized Patients Treated with Paliperidone Palmitate within REACH OUT (Research and Evaluation of Antipsychotic Treatment in Community Behavioral Health Organizations OUTcomes)
- Outcomes among Schizophrenia Patients Recently Hospitalized or Non-Adherent to Antipsychotic Therapy
- Clinical and Social Status of Adults Treated in Substance Abuse Treatment Centers with Possible or Probable Schizophrenia
- Resource Use and Cost in a Randomized, Non-inferiority Trial of Paliperidone Palmitate Three- Versus One-Month Formulations in Patients With Schizophrenia
- Effects of Paliperidone Palmitate Three-Month and One-Month Formulations on Personal and Social Performance Scores in Patients with Schizophrenia: Results from a Randomized, Multicenter, Double-Blind,

Non-inferiority Study

- Symptomatic and Functional Remission in Patients with Schizophrenia after Paliperidone Palmitate Treatment (One-Month and Three-Month Formulations)

Tuesday, May 17

- Evaluation of Paliperidone Palmitate Long-Acting Injectable Therapy in Patients with Schizophrenia by Duration of Illness
- Schizophrenia Disease Course Trajectory and Early Illness Intervention: A Review of the Literature and the Disease Recovery Evaluation and Modification (DREaM) Study Design
- Injection Site Reactions and Pain Associated with Long-Acting Injectable Antipsychotics Paliperidone Palmitate Once-Monthly and Once-Every-Three-Months
- Medicaid Spending Associated with Paliperidone Palmitate or Oral Atypical Antipsychotic Treatment among Adults Recently Diagnosed with Schizophrenia
- Treatment Patterns in Medicaid Patients with Schizophrenia Initiating First- or Second-Generation Long-Acting Injectable vs. Oral Antipsychotics
- Caregiver Burden in Schizophrenia: Pooled Analysis of the Involvement Evaluation Questionnaire Data for Paliperidone Palmitate Three-Month Formulation
- Suicide Ideation and Behavior Assessment Tool (SIBAT): A Novel Measure of Suicidal Ideation/Behavior and Perceived Suicide Risk

About the Janssen Pharmaceutical Companies

At the Janssen Pharmaceutical Companies 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.

IMPORTANT SAFETY INFORMATION AND INDICATION FOR INVEGA TRINZA® (PALIPERIDONE PALMITATE) AND INVEGA SUSTENNA® (PALIPERIDONE PALMITATE)

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.

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.



IMPORTANT SAFETY INFORMATION

INVEGA TRINZA® and 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 TRINZA® and INVEGA SUSTENNA® are not approved for treating dementia-related psychosis.

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

Before you receive INVEGA TRINZA® or 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 TRINZA® or INVEGA SUSTENNA® 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[®] and 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 TRINZA[®] or 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 TRINZA[®] or INVEGA SUSTENNA[®]?

- 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 TRINZA[®] or INVEGA SUSTENNA[®] affects you
- avoid getting overheated or dehydrated

INVEGA TRINZA[®] and 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 TRINZA[®] or 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 TRINZA[®] and 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 TRINZA® include: injection site reactions, weight gain, headache, upper respiratory tract infections, feeling restless 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 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® or INVEGA SUSTENNA®. 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.

This 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.

Please see full Prescribing Information, including Boxed WARNING, for **INVEGA TRINZA®** and **INVEGA SUSTENNA®**

RISPERDAL CONSTA® (risperidone) is used for the treatment of schizophrenia and for the longer-term treatment of Bipolar I Disorder.

IMPORTANT SAFETY INFORMATION FOR RISPERDAL CONSTA®

Elderly Patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death compared to placebo. RISPERDAL CONSTA® (risperidone) is not approved for the treatment of patients with dementia-related psychosis.

Do not receive RISPERDAL CONSTA® if you are allergic to paliperidone, risperidone, or any of the ingredients in RISPERDAL CONSTA®.

Neuroleptic, Malignant Syndrome (NMS) is a rare and potentially fatal side effect reported with RISPERDAL CONSTA® and similar medicines. Call your doctor immediately if the person being treated develops symptoms such as high fever; stiff muscles; shaking; confusion; sweating; changes in pulse, heart rate, or blood pressure; or muscle pain and weakness. Treatment should be stopped if the person being treated has NMS.

Tardive Dyskinesia (TD) is a serious, sometimes permanent side effect reported with RISPERDAL CONSTA® and similar medications. TD includes uncontrollable movements of the face, tongue, and other parts of the body. The risk of developing TD and the chance that it will become permanent is thought to increase with the length of therapy and the overall dose taken by the patient. This condition can develop after a brief period of therapy at low doses, although this is much less common. There is no known treatment for TD, but it may go away partially or completely if therapy is stopped.

Atypical antipsychotic drugs have been associated with metabolic changes that can increase cardiovascular/cerebrovascular risks. These changes may include:

- High blood sugar and diabetes have been reported with RISPERDAL CONSTA® and similar medicines. If you already have diabetes or have risk factors such as being overweight or a family history of diabetes, blood

sugar testing should be done at the beginning and during the treatment. The complications of diabetes can be serious and even life-threatening. Call your doctor if you develop signs of high blood sugar or diabetes, such as being thirsty all the time, having to urinate or "pass urine" more often than usual, or feeling weak or hungry.

- Changes in cholesterol and triglycerides have been noted in patients taking atypical antipsychotics. Check with your doctor while on treatment.
- Weight gain has been reported in patients taking atypical antipsychotics. Monitor weight gain while on treatment.

RISPERDAL CONSTA[®] and similar medications can raise the blood levels of a hormone known as prolactin, causing a condition known as hyperprolactinemia. Blood levels of prolactin remain elevated with continued use. Some side effects seen with these medications include the absence of a menstrual period; breasts producing milk; the development of breasts by males; and the inability to achieve an erection.

Some people taking RISPERDAL CONSTA[®] may feel faint or lightheaded when they stand up or sit up too quickly. By standing up or sitting up slowly and following your healthcare professional's dosing instructions, this side effect can be reduced or it may go away over time.

Blood problems such as low numbers of white blood cells have been reported in patients taking risperidone and similar medications. In some cases it has been serious and life-threatening. Depending upon your medical condition, your doctor may choose to test your blood as you start therapy with RISPERDAL CONSTA[®].

RISPERDAL CONSTA[®] may affect your alertness or driving ability; therefore, do not drive or operate machinery before talking to your healthcare professional.

RISPERDAL CONSTA[®] should be used cautiously in people with a seizure disorder, who have had seizures in the past, or who have conditions that increase their risk for seizures.

Painful, long-lasting erections have been reported with the use of RISPERDAL CONSTA[®]. Call your doctor immediately if you think you are having this problem.

Extrapyramidal Symptoms (EPS) are usually persistent movement disorders or muscle disturbances, such as restlessness, tremors, and muscle stiffness. If you observe any of these symptoms, talk to your healthcare professional.

Inform your healthcare professional if you become pregnant or intend to become pregnant during therapy with RISPERDAL CONSTA[®]. Caution should be used when administering RISPERDAL CONSTA[®] to a nursing woman.

RISPERDAL CONSTA® may make you more sensitive to heat. You may have trouble cooling off, or be more likely to become dehydrated, so take care when exercising or when doing things that make you warm.

Some medications interact with RISPERDAL CONSTA®. Please inform your healthcare professional of any medications or supplements that you are taking. Avoid alcohol while taking RISPERDAL CONSTA®.

In studies of people taking RISPERDAL CONSTA®, the most common side effects in the treatment of schizophrenia were headache, slow movements (including tremor [shaking], stiffness, and a shuffling walk), dizziness, restlessness, tiredness, constipation, indigestion, sleepiness, weight gain, pain in the limbs, and dry mouth.

In studies of people taking RISPERDAL CONSTA®, the most common side effects in the treatment of bipolar disorder were weight gain (when used alone) and slow movements (including with tremor [shaking], stiffness, and a shuffling walk) and tremor (when used with lithium or valproate).

This is not a complete list of all possible side effects. Ask your doctor or treatment team if you have any questions or want more information.

If you have any questions about RISPERDAL CONSTA® or your therapy, talk with your doctor.

You are encouraged to report negative 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 **RISPERDAL CONSTA®**.

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