NEWS RELEASE

Janssen Initiates FIRST, a Novel Study to Evaluate the Benefit of Caregiver Education in Improvement of Outcomes for Patients with Serious Mental Illness

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Titusville, NJ, September 15, 2015 - Today, Janssen Pharmaceuticals, Inc. announced the initiation of the FIRST (Family Intervention in Recent Onset Schizophrenia Treatment) study at the 28th Annual U.S. Psychiatric and Mental Health Congress. FIRST examines the value of tailored psycho-education and skills training in reducing the burden on caregivers and improving treatment and recovery for patients diagnosed with schizophrenia, schizoaffective or schizophreniform disorder.

These serious mental illnesses often begin in early adulthood, just as individuals are establishing their independence and while caregivers still play a large role in patients' daily lives. Caregivers, like patients, can also benefit from support that is provided to them.

FIRST will evaluate the role of interactive, internet-based psycho-education and skills training for caregivers. Caregiver concerns about privacy, stigma, and the time commitment required for education and training have historically presented significant challenges to studying the impact of these programs on caregiver burden. Internet-based education may alleviate some of these concerns because they offer more privacy, discretion and flexible scheduling.

This innovative study will also include an exploratory analysis to assess the impact of this type of education and training in patients receiving long-acting paliperidone palmitate therapies or oral antipsychotic treatment.

"FIRST represents Janssen's commitment to improving quality outcomes for people and families living with mental illnesses by researching real-world issues beyond symptom reduction," said Michelle Kramer, Vice President, U.S. Neuroscience Medical Affairs, Janssen. "Although caregiver burden is widely recognized, this is the first study that examines the link between caregiver education and patient stability to determine if educating caregivers and helping them learn new skills will result in improved patient outcomes."

About the FIRST Study

The open-label FIRST study will enroll approximately 300 patient-caregiver pairs and assess both patient outcomes and caregiver burden over a 12-month period. The pairs will be stratified by treatment type - INVEGA SUSTENNA® (paliperidone palmitate), a once monthly injection; INVEGA TRINZA&#8482 (paliperidone palmitate), a three-month injection; or oral antipsychotic treatment - as prescribed by their treating clinicians as part of usual clinical practice. The caregivers will be randomized to receive either up to 16 sessions of individualized psycho-education and skills training provided by a trained clinician via interactive online technology or the customary caregiver support provided by the study site. The primary outcome measure is number of patient treatment failures over 12 months. Secondary measures include: number of patient treatment failures over 12 months in patients receiving INVEGA SUSTENNA®, INVEGA TRINZA&#8482, or oral antipsychotic treatment; caregiver-reported outcomes assessing burden on their psychological and physical well-being; and patients' overall illness severity as determined by a clinician-rated Clinical Global Impression - Severity (CGI -S) assessment. Assessments will occur at baseline, three, six and 12 months. FIRST is planned to be conducted at 30 sites that represent "real world" settings, primarily community mental health centers, as well as some academic research centers.

Prior to the initiation of the study, the FIRST methodology was presented at the annual American Society of Clinical Psychopharmacology meeting in June.

About Schizophrenia, Schizoaffective Disorder and Schizophreniform Disorder

Schizophrenia affects approximately 2.4 million U.S. adults. 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. Schizophreniform disorder is characterized by the presence of the symptoms of schizophrenia, but it is distinguished by its shorter duration, which is at least one month but less than 6 months. Sometimes mistaken for schizophrenia, schizoaffective disorder is a mental condition characterized by a loss of contact with reality - psychosis - and mood symptoms of depression and/or mania. One million adults in the United States are living with this condition.

About INVEGA TRINZA&#8482

INDICATION

INVEGA TRINZA&#8482 (paliperidone palmitate) is a prescription medicine given by injection every three months by a healthcare professional and used to treat schizophrenia. INVEGA TRINZA&#8482 is used in people who have been treated with INVEGA SUSTENNA® (paliperidone palmitate) once a month for at least four months.

IMPORTANT SAFETY INFORMATION

INVEGA TRINZA&#8482 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&#8482 is not approved for treating dementia-related psychosis.

Do not receive INVEGA TRINZA&#8482 if you are allergic to paliperidone palmitate, risperidone, or any of the ingredients in INVEGA TRINZA&#8482. See end of the Patient Information leaflet in the full Prescribing Information for a complete list of INVEGA TRINZA&#8482 ingredients.

Before you receive INVEGA TRINZA&#8482, 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&#8482 will harm your unborn baby
    - If you become pregnant while taking INVEGA TRINZA&#8482, 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&#8482 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&#8482 can pass into your breast milk and may harm your baby. You and your healthcare provider should decide if you will receive INVEGA TRINZA&#8482 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&#8482?

- INVEGA TRINZA&#8482 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&#8482 affects you
- avoid getting overheated or dehydrated

INVEGA TRINZA&#8482 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&#8482. 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&#8482 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&#8482 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&#8482. 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&#8482.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use INVEGA TRINZA&#8482 for a condition for which it was not prescribed. Do not give INVEGA TRINZA&#8482 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&#8482 that is written for health professionals.

The Patient Information leaflet summarizes the most important information about INVEGA TRINZA&#8482. 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 TRINZA&#8482 (paliperidone palmitate) at **www.JanssenCNS.com/InvegaSustenna** and **www.InvegaTrinzaHCP.com**.

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