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Janssen Signs Results-Based Contract with Oklahoma Health Care Authority (OHCA) for its Long-Acting Injectable Schizophrenia Medicines

With INVEGA SUSTENNA® and INVEGA TRINZA®, medicines shown to delay patient relapse, OHCA aims to reduce Medicaid costs, improve patient care

TITUSVILLE, N.J., December 13, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today a results-based contract for long-acting injectable schizophrenia medicines (LAIs) with the Oklahoma Health Care Authority (OHCA), which manages Oklahoma’s Medicaid plan, SoonerCare. The agreement was made between Janssen Pharmaceuticals, Inc. and OHCA.

[Click to Tweet:](#) .@JanssenUS signed a results-based agreement with @OKSoonerCare aimed at helping to improve care and reduce Medicaid costs for people living with #schizophrenia <http://po.st/MUWq5V>

Under this arrangement focused on enabling the use of INVEGA SUSTENNA® (paliperidone palmitate) and INVEGA TRINZA® (paliperidone palmitate) earlier in treatment of adults with schizophrenia, OHCA aims to improve care among patients with schizophrenia and reduce expenses for medical services. The agreement enables potential cost savings for OHCA for these medicines.

“Oklahoma is excited to work with a major manufacturer like Janssen,” said Nancy Nesser, J.D., Pharm.D., OHCA Pharmacy Director. “INVEGA SUSTENNA® has been shown to delay time to relapse and hospitalization compared to a group of oral antipsychotics, providing a significant opportunity to curb medical costs. And this, along with improved health care, is our goal for SoonerCare members.”

A comparative effectiveness [study](#) found that the long-acting treatment INVEGA SUSTENNA® demonstrated superiority versus a group of seven commonly prescribed oral treatments in delaying time to relapse. Additionally, the time to first psychiatric hospitalization or arrest and/or incarceration was significantly longer for people treated with INVEGA SUSTENNA® compared to those treated with commonly prescribed oral

antipsychotics. 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.

A retrospective Medicaid claims analysis showed that INVEGA SUSTENNA[®] can lead to cost offsets in Medicaid programs.ⁱ Analysis of multistate data from Medicaid programs shows INVEGA SUSTENNA[®] was associated with a 36 percent reduction (per patient per month) in risk for all-cause hospitalization when compared to oral antipsychotics over a 12-month period.

INVEGA TRINZA[®] is the first and only schizophrenia treatment that is administered only four times a year, after patients have been adequately treated with INVEGA SUSTENNA[®] for at least four months. In a clinical trial, the median time to relapse in the INVEGA TRINZA[®] arm could not be estimated due to low percentage (7.4 percent) of patients with relapse.

In June 2018, Oklahoma became the first state to apply for and win approval from its federal partner, the Centers for Medicare & Medicaid Services (CMS), to pursue Medicaid supplemental results-based agreements with pharmaceutical manufacturers.

“With health care costs a concern nationwide, we’re excited to be working with Oklahoma to expand patient access to these transformational medicines that can play a role in making public programs more sustainable,” said Blasine Penkowski, Chief Strategic Customer Officer, Johnson & Johnson Health Care Systems Inc. “We’re pleased that Oklahoma sees their clinical and economic value and their potential to reduce costs by improving care for patients with schizophrenia.”

The agreement reflects Janssen’s [commitment](#) to moving to a results-based health care system that will help control cost while delivering better quality care.

More Information About INVEGA TRINZA[®] and 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 May 2015, the U.S. FDA approved INVEGA TRINZA[®] (paliperidone palmitate), the first and only schizophrenia treatment to be administered four times a year.

INDICATIONS

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) is a prescription medicine given by injection by a healthcare professional. INVEGA SUSTENNA[®] is used to treat schizophrenia in adults.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about INVEGA TRINZA[®] and INVEGA SUSTENNA[®]?
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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 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 the 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 professional 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® or INVEGA SUSTENNA®, talk to your healthcare professional 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® or INVEGA SUSTENNA® may experience symptoms such as tremors, irritability, excessive sleepiness, eye twitching, muscle spasms, decreased appetite, difficulty breathing, or abnormal movement of arms and legs. Let your healthcare professional know if these symptoms occur.
- are breastfeeding or plan to breastfeed. INVEGA TRINZA® or INVEGA SUSTENNA® can pass into your breast milk. Talk to your healthcare professional about the best way to feed your baby if you receive INVEGA TRINZA® or INVEGA SUSTENNA®.

Tell your healthcare professional 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 professional 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 professional for the potential risk of falls.

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:

- **See “What is the most important information I should know about INVEGA TRINZA® and 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 TRINZA® or INVEGA SUSTENNA®. NMS can cause death and must be treated in a hospital. Call your healthcare professional 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 professional 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® or 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 professional 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 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.

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 professional 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 professional or pharmacist.

Call your healthcare professional 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® or INVEGA SUSTENNA®

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use INVEGA TRINZA® or INVEGA SUSTENNA® for a condition for which it was not prescribed. Do not give INVEGA TRINZA® or 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 professional for information about INVEGA TRINZA® or INVEGA SUSTENNA® that is written for healthcare professionals.

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

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

Please see the full Prescribing Information, including Boxed WARNING, for INVEGA TRINZA® available [here](#) and INVEGA SUSTENNA® available [here](#), and discuss any questions you have with your healthcare professional.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

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® and INVEGA TRINZA® in the United States.

ⁱ Pesa JA, Muser E, Montejano LB, et al. Costs and resource utilization among Medicaid patients with schizophrenia treated with paliperidone palmitate or oral atypical antipsychotics. *Drugs Real World Outcomes*. 2015;2(4):377-385.