INVEGA® SUSTENNA® Three-Month Formulation of Paliperidone Palmitate Enters Phase 3 Clinical Program for Schizophrenia

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DUBLIN--(BUSINESS WIRE)--Jun. 12, 2012-- Alkermes plc (NASDAQ: ALKS) today announced that Janssen Research & Development, LLC has initiated a phase 3 clinical research program for a three-month formulation of INVEGA® SUSTENNA® (paliperidone palmitate), an injectable medicine for the treatment of schizophrenia. The investigational product is being developed by Janssen Pharmaceutica, NV, licensee to Alkermes' proprietary technology for nanoparticles. Two phase 3 studies are expected to enroll approximately 1,800 patients with schizophrenia and will assess the efficacy, safety and tolerability of the three-month injectable formulation. These clinical studies are expected to be completed in the second half of calendar 2014.

"The development of a three-month formulation of INVEGA SUSTENNA represents a first for the field of atypical antipsychotics and builds on Alkermes' expertise in long-acting technologies," said Dr. Elliot Ehrich, Chief Medical Officer at Alkermes. "Patients and physicians have a keen interest in new treatment options for schizophrenia. A three-month formulation of a long-acting atypical antipsychotic could significantly advance the treatment paradigm for schizophrenia, and we are looking forward to seeing the results from these phase 3 studies of INVEGA SUSTENNA."

INVEGA SUSTENNA was approved as a once-monthly injectable medication for schizophrenia in the U.S. in 2009. It was also approved in the EU in 2011, where it is available under the trade name XEPLION®. INVEGA SUSTENNA is marketed worldwide by the Janssen Pharmaceutical Companies. INVEGA SUSTENNA incorporates Alkermes' proprietary technology for nanoparticles, and Alkermes earns a royalty on worldwide sales of the product.

Phase 3 Program

Two phase 3 studies of the three-month formulation of INVEGA SUSTENNA have been initiated and are expected to enroll approximately 1,800 patients with schizophrenia.

The first study is a randomized, multicenter, double-blind, parallel-group, fixed-dose, relapse-prevention study and will explore the efficacy, safety and tolerability of the three-month formulation of INVEGA SUSTENNA, compared to placebo. Approximately 500 patients with schizophrenia will be enrolled in the study. The primary efficacy endpoint of the study is time to first relapse event during the double-blind phase.

The second phase 3 study is a randomized, double-blind, parallel-group, multicenter, non-inferiority study comparing the three-month and one-month formulations of INVEGA SUSTENNA. Approximately 1,300 patients with schizophrenia will be enrolled in the study. The primary efficacy endpoint of the study is the percentage of patients who have not relapsed at the end of the 48-week, double-blind portion of the study.

About Schizophrenia

Schizophrenia is a chronic, severe and disabling brain disorder. The disease is marked by positive symptoms (hallucinations and delusions) and negative symptoms (depression, blunted emotions and social withdrawal), as well as by disorganized thinking. An estimated 2.4 million Americans have schizophrenia[1], with men and women affected equally. Worldwide, it is estimated that one person in every 100 develops schizophrenia, which is one of the most serious types of mental illness.

About INVEGA® SUSTENNA®

INVEGA SUSTENNA is a type of prescription medicine called an atypical antipsychotic given as an injection by a healthcare provider. INVEGA SUSTENNA is used to treat symptoms of schizophrenia and can also be used to lessen the chance of schizophrenia symptoms from coming back. The exact way INVEGA SUSTENNA works is not known. INVEGA SUSTENNA is thought to help restore the balance of certain chemicals in the brain, and has been shown to help many people manage their symptoms of schizophrenia.

Important Safety Information for INVEGA® SUSTENNA®

INVEGA® SUSTENNA® (paliperidone palmitate) is used for the treatment of schizophrenia.

IMPORTANT SAFETY INFORMATION FOR INVEGA® SUSTENNA®

INVEGA® SUSTENNA® is not approved for the treatment of dementia-related psychosis in elderly patients. Elderly patients who were given oral antipsychotics like INVEGA® SUSTENNA® in clinical studies for psychosis caused by dementia (memory problems) had a higher risk of death.

Neuroleptic Malignant Syndrome (NMS) is a rare, but serious side effect that could be fatal and has been reported with INVEGA® SUSTENNA® and similar medicines. Call your doctor right away if you develop symptoms such as a high fever, rigid muscles, shaking, confusion, sweating more than usual, increased heart rate or blood pressure, or muscle pain or weakness. Treatment should be stopped if you are being treated for NMS.

Tardive Dyskinesia (TD) is a rare, but serious and sometimes permanent side effect reported with INVEGA® SUSTENNA® and similar medicines. Call your doctor right away if you start to develop twitching or jerking movements that you cannot control in your face, tongue, or other parts of your 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 total dose received.

This condition can also develop after a short period of treatment at low doses, but this is less common. There is no known treatment for TD, but it may go away partially or completely if the medicine is stopped.

One risk of INVEGA® SUSTENNA® is that it may change your heart rhythm. This effect is potentially serious. You should talk to your doctor about any current or past heart problems. Because these problems could mean you're having a heart rhythm abnormality, contact your doctor **IMMEDIATELY** if you feel faint or feel a change in the way that your heart beats (palpitations).

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 INVEGA® SUSTENNA® 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.

Some people may feel faint, dizzy, or may pass out when they stand up or sit up suddenly. Be careful not to get up too quickly. It may help if you get up slowly and sit on the edge of the bed or chair for a few minutes before you stand up. These symptoms may decrease or go away after your body becomes used to the medicine.

INVEGA® SUSTENNA® and similar medicines have been associated with decreases in the counts of white cells in circulating blood. If you have a history of low white blood cell counts or have unexplained fever or infection, then please contact your doctor right away.

INVEGA® SUSTENNA® and similar medicines can raise the blood levels of a hormone called prolactin, and blood levels of prolactin remain high with continued use. This may result in some side effects including missed menstrual periods, leakage of milk from the breasts, development of breasts in men, or problems with erection.

If you have a prolonged or painful erection lasting more than 4 hours, seek immediate medical help to avoid long-term injury.

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

INVEGA® SUSTENNA® can make some people feel dizzy, sleepy, or less alert. Until you know how you are going to respond to INVEGA® SUSTENNA®, be careful driving a car, operating machines, or doing things that require you to be alert.

This medicine may make you more sensitive to heat. You may have trouble cooling off or be more likely to become dehydrated. Be careful when you exercise or spend time doing things that make you warm.

Some medications interact with INVEGA® SUSTENNA®. Please inform your healthcare professional of any medications or supplements that you are taking.

INVEGA® SUSTENNA® 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.

Inform your healthcare professional if you become pregnant or intend to become pregnant during therapy with INVEGA® SUSTENNA®.

Do not drink alcohol while you are taking INVEGA® SUSTENNA®.

In a study of people taking INVEGA® SUSTENNA®, common side effects in the treatment of schizophrenia were reactions at the injection site, sleepiness, dizziness, feeling of inner restlessness, and abnormal muscle movements, including tremor (shaking), shuffling, uncontrolled involuntary movements, and abnormal movements of the eyes.

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 INVEGA® SUSTENNA® or your therapy, talk with your doctor.

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

Please see the Important Product Information.

About Alkermes plc

Alkermes plc is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to develop innovative medicines that improve patient outcomes. The company has a diversified portfolio of more than 20 commercial drug products and a substantial clinical pipeline of product candidates that address central nervous system (CNS) disorders such as addiction, schizophrenia and depression. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts and manufacturing facilities in Athlone, Ireland; Gainesville, Georgia; and Wilmington, Ohio. For more information, please visit Alkermes' website at http://www.alkermes.com/.

Note Regarding Forward-Looking Statements

Certain statements set forth above may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to: the timing, size and scope of the planned phase 3 clinical studies for a three-month formulation of paliperidone palmitate for the treatment of schizophrenia and the potential safety, efficacy and tolerability of such three-month formulation. Although the company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees. The company's business is subject to significant risk and uncertainties and there can be no assurance that its actual results will not differ materially from its expectations.

These risks and uncertainties include, among others: whether preclinical and early clinical results for the three-month formulation of INVEGA SUSTENNA will be predictive of future clinical study results; whether the three-month formulation of INVEGA SUSTENNA is shown to be ineffective or unsafe during clinical studies; decisions by the FDA or foreign regulatory authorities regarding the three-month formulation of INVEGA SUSTENNA for the treatment of schizophrenia; potential changes in cost, scope and duration of the phase 3 clinical trials of the three-month formulation of INVEGA SUSTENNA for the treatment of schizophrenia; and those risks described in the Alkermes plc Annual Report on Form 10-K for the year ended March 31, 2012 and in other filings made by the company with the Securities and Exchange Commission ("SEC"), which are available at the SEC's website at http://www.sec.gov/. The information contained in this press release is provided by the company as of the date hereof, and, except as required by law, the company disclaims any intention or responsibility for updating any forward-looking information contained in this press release.

[1]National Institutes of Health. Accessed on June 8, 2012 from http://report.nih.gov/NIHfactsheets/ViewFactSheet.aspx?csid=67&key=S#S.

Source: Alkermes plc

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