NEWS RELEASE

Study Published in The Journal of Clinical Psychiatry Shows INVEGA SUSTENNA® Effective Six Months Longer Than Common Oral Antipsychotics in Treatment of Schizophrenia

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Trial is the first to study schizophrenia treatment within the context of many real-world issues faced by patients with schizophrenia

TITUSVILLE, N.J., April 15, 2015 - A study published in **The Journal of Clinical Psychiatry** yesterday shows that long-acting INVEGA SUSTENNA® (paliperidone palmitate) was effective six months longer than commonly prescribed oral antipsychotics in patients with schizophrenia, delaying relapse such as hospitalization, arrest and incarceration. Conducted over a 15-month period, the Paliperidone Palmitate Research In Demonstrating Effectiveness (PRIDE) study is the first prospective, randomized clinical trial to study schizophrenia treatments within the context of many real-world issues faced by patients in their daily lives, including challenging situations such as recent incarceration or substance abuse.

"Janssen designed and executed this innovative trial to account for the real-world context in which those living with schizophrenia and their families seek treatment options," said trial co-author Larry Alphs, MD, PhD, Psychiatry Therapeutic Team Lead, Medical Affairs, Janssen Pharmaceuticals, Inc. "This clinical trial showed that INVEGA SUSTENNA® effectively treats patients with schizophrenia six months longer than oral antipsychotics, which is incredibly meaningful for patients, their caregivers and providers as they explore treatment options."

The FDA is currently reviewing a supplemental New Drug Application (sNDA) to update the INVEGA SUSTENNA®

label to include data from this trial. The sNDA was filed in July 2014, and the action date for this application is May 11, 2015.

"Across the U.S., seriously mentally ill persons, including persons with schizophrenia, are three times more likely to be in jail or prison versus being in a hospital, creating a large and costly problem for the U.S. healthcare system," said trial investigator Jason Bermak, MD, PhD, Medical Director of SF-CARE, Inc. "This study addresses the fact that the lack of consistent treatment can put patients at risk for relapse, possibly leading to incarceration, hospitalization and other serious consequences. However, with proper treatment and support, individuals living with schizophrenia can and do live meaningful lives."

Trial Design The trial was a 15-month multicenter, prospective, randomized, open-label, active-controlled study of 444 adults with schizophrenia that was designed to reflect real-world management of schizophrenia. Real world is defined by the patients included in the trial, the broad flexibility in medication options, and measurement of common outcomes in this population, such as incarceration and hospitalization.

Participants were enrolled at 50 sites across 25 U.S. states and Puerto Rico. To enhance enrollment of individuals who are often excluded from trials, efforts were made to recruit participants from nontraditional locations, such as homeless shelters, soup kitchens, and jail-release or diversion programs. Therefore, trial participants included those with a recent history of incarceration, who had self-reported substance or alcohol abuse just prior to trial enrollment, or had a current diagnosis of a substance abuse disorder. This patient population is more reflective of real-world clinical practice than that which is typically recruited for clinical trials.

Participants were randomized to either monthly INVEGA SUSTENNA® (78-234 mg) or one of seven flexibly-dosed, common daily oral antipsychotic medications prescribed in the U.S., including aripiprazole, haloperidol, olanzapine, paliperidone, perphenazine, quetiapine and risperidone. The study was not powered to compare effectiveness of INVEGA SUSTENNA® with that of individual oral antipsychotics.

Trial Results Study results indicate that INVEGA SUSTENNA® delayed relapse for a significantly longer time period than did oral treatment (median 416 days vs. median 226 days; P = 0.011).

The primary study endpoint was the length of time to the first treatment failure or relapse. In this study, treatment failure was defined as psychiatric hospitalization; arrest/incarceration; suicide; treatment supplementation or discontinuation of antipsychotic medication due to inadequate efficacy, safety concerns or tolerability issues; or increased psychiatric services to prevent psychiatric hospitalization. Arrest/incarceration and psychiatric hospitalization were the most common reasons for treatment failure in the paliperidone palmitate and oral antipsychotic groups (21.2 percent vs. 29.4 percent and 8.0 percent vs. 11.9 percent, respectively).

No new safety issues were observed during the study. During the trial, commonly reported treatment-emergent adverse events (≥10% of INVEGA SUSTENNA® patients) included injection site pain; insomnia; weight increase; akathisia, which is a feeling of inner restlessness or needing to be constantly moving; and anxiety.

About Schizophrenia Schizophrenia is a complex and chronic brain disorder that can be severe and disabling. It affects approximately 2.4 million U.S. adults, often beginning in the late teens or early 20s. The disease typically manifests as hallucinations, delusions, and disorganized thoughts and behavior.

Because there are currently no physical or laboratory tests that diagnose this condition, schizophrenia is diagnosed by the presence of symptoms. Researchers have identified various risk factors for this disease, including heredity and certain genetic risk factors, and environmental factors, such as social stress, isolation and drug use. If left untreated, schizophrenia can greatly interfere with education, employment and interpersonal functioning. The course of schizophrenia is varied, generally involving a series of relapses or the return of symptoms after partial recovery.

About 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. Late last year the FDA approved INVEGA SUSTENNA® for the treatment of schizoaffective disorder, making it the first and only once-monthly medication to treat this condition; however, this population was not studied as part of the PRIDE trial.

About Janssen Pharmaceuticals, Inc. Janssen Pharmaceuticals, Inc. is dedicated to addressing and resolving the major unmet medical needs of our time. Also driven by its commitment to patients, healthcare professionals, and caregivers, Janssen strives to develop sustainable and integrated healthcare solutions by working in partnership with all stakeholders on the basis of trust and transparency. The company's daily work is guided by meeting goals of excellence in quality, innovation, safety and efficacy in order to advance patient care. Janssen provides medicines for an array of illnesses and disorders in several therapeutic areas. For more information on Janssen Pharmaceuticals, Inc., visit **www.JanssenPharmaceuticalsInc.com** or follow Janssen on Twitter at **www.twitter.com/JanssenUS** and on YouTube at **https://www.youtube.com/user/JanssenUS**.

Janssen Pharmaceuticals, Inc. is part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Janssen Pharmaceuticals, Inc. markets INVEGA SUSTENNA® in the United States.

INVEGA SUSTENNA® (paliperidone palmitate) is indicated for the treatment of:

- Schizophrenia.
- Schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers or antidepressants.

IMPORTANT SAFETY INFORMATION FOR INVEGA SUSTENNA® (paliperidone palmitate)

Contraindications: Paliperidone is contraindicated in patients with a known hypersensitivity to either paliperidone, risperidone, or to any excipients of the formulation.

Cerebrovascular Adverse Reactions: Cerebrovascular adverse reactions (e.g., stroke, transient ischemic attacks), including fatalities, were reported in placebo-controlled trials in elderly patients with dementia-related psychosis taking oral risperidone, aripiprazole, and olanzapine. The incidence of cerebrovascular adverse reactions was significantly higher than with placebo. INVEGA SUSTENNA® is not approved for the treatment of patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): NMS, a potentially fatal symptom complex, has been reported with the use of antipsychotic medications, including paliperidone. Clinical manifestations include muscle rigidity, fever, altered mental status, and evidence of autonomic instability (see full Prescribing Information). Management should include immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy, intensive symptomatic treatment and close medical monitoring, and treatment of any concomitant serious medical problems.

QT Prolongation: Paliperidone causes a modest increase in the corrected QT (QTc) interval. Avoid the use of drugs that also increase QTc interval and in patients with risk factors for prolonged QTc interval. Paliperidone should also be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias. Certain circumstances may increase the risk of the occurrence of torsades de pointes and/or sudden death in association with the use of drugs that prolong the QTc interval.

Tardive Dyskinesia (TD): TD is a syndrome of potentially irreversible, involuntary, dyskinetic movements that may develop in patients treated with antipsychotic medications. The risk of developing TD and the likelihood that dyskinetic movements will become irreversible are believed to increase with duration of treatment and total cumulative dose, but can develop after relatively brief treatment at low doses. Elderly female patients appeared to be at increased risk for TD, although it is impossible to predict which patients will develop the syndrome. Prescribing should be consistent with the need to minimize the risk of TD (see full Prescribing Information). Discontinue drug if clinically appropriate. The syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and body weight gain. While all of the drugs in the class have been shown to produce some metabolic changes, each

drug has its own specific risk profile.

Hyperglycemia and Diabetes Mellitus: Hyperglycemia and diabetes mellitus, in some cases extreme and associated with ketoacidosis, hyperosmolar coma or death, have been reported in patients treated with all atypical antipsychotics (APS). Patients starting treatment with APS who have or are at risk for diabetes mellitus should undergo fasting blood glucose testing at the beginning of and during treatment. Patients who develop symptoms of hyperglycemia during treatment should also undergo fasting blood glucose testing. All patients treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia. Some patients require continuation of antidiabetic treatment despite discontinuation of the suspect drug.

Dyslipidemia: Undesirable alterations have been observed in patients treated with atypical antipsychotics.

Weight Gain: Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Orthostatic Hypotension and Syncope: INVEGA SUSTENNA® may induce orthostatic hypotension in some patients due to its alpha-blocking activity. INVEGA SUSTENNA® should be used with caution in patients with known cardiovascular disease, cerebrovascular disease or conditions that would predispose patients to hypotension (e.g., dehydration, hypovolemia, treatment with antihypertensive medications). Monitoring should be considered in patients for whom this may be of concern.

Leukopenia, Neutropenia and Agranulocytosis have been reported with antipsychotics, including paliperidone. Patients with a history of clinically significant low white blood cell count (WBC) or drug-induced leukopenia/neutropenia should have frequent complete blood cell counts during the first few months of therapy. At the first sign of a clinically significant decline in WBC, and in the absence of other causative factors, discontinuation of INVEGA SUSTENNA® should be considered. Patients with clinically significant neutropenia should be carefully monitored for fever or other symptoms or signs of infection and treated promptly if such symptoms or signs occur. Patients with severe neutropenia (absolute neutrophil count <1000/mm3) should discontinue INVEGA SUSTENNA® and have their WBC followed until recovery.

Hyperprolactinemia: As with other drugs that antagonize dopamine D2 receptors, INVEGA SUSTENNA® elevates prolactin levels, and the elevation persists during chronic administration. Paliperidone has a prolactin-elevating effect similar to risperidone, which is associated with higher levels of prolactin elevation than other antipsychotic agents.

Potential for Cognitive and Motor Impairment: Somnolence, sedation, and dizziness were reported as adverse reactions in subjects treated with INVEGA SUSTENNA®. INVEGA SUSTENNA® has the potential to impair

judgment, thinking, or motor skills. Patients should be cautioned about performing activities that require mental alertness such as operating hazardous machinery, including motor vehicles, until they are reasonably certain that INVEGA SUSTENNA® does not adversely affect them.

Seizures: INVEGA SUSTENNA® should be used cautiously in patients with a history of seizures or with conditions that potentially lower seizure threshold. Conditions that lower seizure threshold may be more prevalent in patients 65 years or older.

Administration: For intramuscular injection only by a healthcare professional. Care should be taken to avoid inadvertent injection into a blood vessel.

Drug Interactions: Strong CYP3A4/P-glycoprotein (P-gp) inducers: It may be necessary to increase the dose of INVEGA SUSTENNA® when a strong inducer of both CYP3A4 and P-gp (e.g. carbamazepine, rifampin, St. John's wort) is co-administered. Conversely, on discontinuation of the strong inducer, it may be necessary to decrease the dose of INVEGA SUSTENNA®.

Pregnancy/Nursing: Patients should be advised to notify their physician if they become pregnant/intend to become pregnant or intend to nurse during treatment with INVEGA SUSTENNA®.

Commonly Observed Adverse Reactions for INVEGA SUSTENNA®: The most common adverse reactions in clinical trials in patients with schizophrenia (≥10%5% and twice placebo) were injection site reactions, somnolence/sedation, dizziness, akathisia and extrapyramidal disorder. No adverse events occurred at a rate of ≥10%5% and twice placebo during the long-term double-blind, placebo-controlled study in patients with schizoaffective disorder. The following adverse reactions occurred more frequently (a ≥10%2% difference vs. placebo) in the long-term study in patients with schizoaffective disorder: weight increased, nasopharyngitis, headache, hyperprolactinemia, and pyrexia.

Please see full Prescribing Information including Boxed Warning for INVEGA SUSTENNA® (paliperidone palmitate) and INVEGA® (paliperidone) at **http://www.JanssenCNS.com/InvegaSustenna** and **www.JanssenCNS.com/Invega**.

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development. 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: challenges inherent in new product development, including obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; challenges to

patents; 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.

Media Contact: Robyn Frenze 609-730-3468 (office) 215-370-7322 (mobile)

Investor Contacts: Louise Mehrotra 732-524-6491 (office)

Lesley Fishman 732-524-3922 (office)