NEWS RELEASE

FDA Grants Priority Review for Three-Month Paliperidone Palmitate for the Treatment of Schizophrenia

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TITUSVILLE, N.J., January 19, 2015 - Janssen Research & Development, LLC (Janssen) announced today that the U.S. Food and Drug Administration (FDA) has granted Priority Review for the New Drug Application (NDA) for three-month atypical antipsychotic paliperidone palmitate to treat schizophrenia in adults. If approved, it will be the first and only long-acting atypical antipsychotic that has a dosing schedule of just four times a year.

Priority Review is a designation for a drug that treats a serious condition and, if approved, would provide significant improvement in safety or effectiveness. A priority review designation means FDA's goal is to take action on the marketing application within six months of receipt as compared to 10 months under standard review.

"If approved, this three-month formulation adds an unprecedented treatment option to help address the needs of people living with schizophrenia by providing a new, less frequently dosed treatment choice," said Husseini K. Manji, M.D., Global Head, Neuroscience Therapeutic Area, Janssen Research & Development, LLC. "New treatments give patients, and caregivers, a broader range of options to address their needs as early as possible in their recovery journeys."

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. 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 disease after partial recovery.

The filing was based on a Phase 3, international, randomized, multicenter, double-blind, relapse prevention study of paliperidone palmitate three-month injection. The study, which included more than 500 patients, evaluated the efficacy of three-month paliperidone palmitate compared with placebo in delaying time to first occurrence of relapse symptoms of schizophrenia. Study patients who were randomized to treatment were stabilized with INVEGA® SUSTENNA® (once monthly paliperidone palmitate), an approved treatment for schizophrenia, prior to receiving the investigational three-month formulation. The study was stopped early for positive efficacy after an interim review of the data by an Independent Data Monitoring Committee based on pre-specified criteria, specifically achieving a statistically significant difference from placebo in delaying time to relapse. Based on this study, the safety profile of paliperidone palmitate three-month formulation is consistent with that of once monthly 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.

INVEGA® SUSTENNA® and three-month paliperidone palmitate utilize Alkermes' proprietary NanoCrystal® technology, which enables solubility of poorly water-soluble compounds.

For additional study information, visit **ClinicalTrials.gov**.

About Janssen Research & Development, LLC

Janssen Research & Development, LLC, is headquartered in Raritan, N.J., and has affiliated facilities in Europe, the United States and Asia. Driven by its commitment to patients, Janssen Research & Development works to bring innovative ideas, products, services and solutions to address serious unmet medical needs around the world. The company is leveraging a combination of internal and external innovation to discover and develop novel medicines and solutions in five distinct therapeutic areas: Neuroscience, Oncology, Immunology, Infectious Diseases and Vaccines, and Cardiovascular and Metabolism. For more information about Janssen Research & Development, LLC visit **www.janssenrnd.com**.

Janssen Research & Development, LLC is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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/mm^3) should discontinue INVEGA® SUSTENNA® and have their WBC followed until recovery.

Hyperprolactinemia: As with other drugs that antagonize dopamine D_2 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 (≥5% and twice placebo) were injection site reactions, somnolence/sedation, dizziness, akathisia and extrapyramidal disorder. No adverse events occurred at a rate of ≥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 ≥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 **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 Research & Development, LLC 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 laws and regulations, including domestic and foreign 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 29, 2013, 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.)

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