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Janssen Pharmaceuticals Seeks Expanded Label for Once-Monthly INVEGA® SUSTENNA® (paliperidone palmitate) to Show Delayed Time to Relapse Compared to Daily Oral Schizophrenia Therapies

Submission based on first head-to-head study vs. oral treatments in real world context

Titusville, NJ, July 14, 2014 – Janssen Pharmaceuticals, Inc. today announced the submission of a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) seeking a label change that, if approved, would include new data showing significantly delayed time to relapse in patients prescribed once-monthly atypical long-acting antipsychotic INVEGA® SUSTENNA® (paliperidone palmitate) compared to selected oral antipsychotic therapies in the treatment of schizophrenia. The sNDA is supported by the landmark **P**aliperidone Palmitate **R**esearch **I**n **D**emonstrating **E**ffectiveness study (PRIDE), which is the first prospective, randomized clinical trial to evaluate schizophrenia treatments within the context of many "real world" issues faced by patients in their daily lives, including one of the most challenging circumstances – recent incarceration.

"Lack of consistent treatment, when and where people with schizophrenia need it, can put patients at risk for relapse, possibly leading to disability, homelessness, incarceration and other serious consequences," said Michelle Kramer, Vice President, U.S. Neuroscience Medical Affairs, Janssen. "The PRIDE study shows that INVEGA® SUSTENNA® can play a valuable role in providing much needed consistent treatment."

Schizophrenia is a chronic brain disorder that can be severe and disabling. The course of schizophrenia is varied for some patients, often fluctuating between a series of relapses, or return of disease after partial recovery. While there is no cure, individuals working with their treatment teams can live meaningful lives with a treatment regimen that may include medication and

psychotherapy. Medication, including daily pills or long-acting monthly therapy, is the mainstay treatment for symptoms.

PRIDE was a 15-month U.S. multicenter, prospective, randomized, open-label, blinded, active-controlled study of 444 adults with schizophrenia and a recent history of incarceration. PRIDE assessed as its primary endpoint time to treatment failure, which is a subset of relapse. In this study, this endpoint was defined as any one of the following: psychiatric hospitalization; arrest/incarceration; suicide; treatment supplementation or discontinuation of antipsychotic medication because of inadequate efficacy, safety concerns or tolerability issues; or increased level of psychiatric services to prevent psychiatric hospitalization. Treatment failure was determined by an Event Monitoring Board that was blinded to treatment assignment. INVEGA® SUSTENNA® delayed relapse for a statistically significantly longer time period than did oral treatment (median 416 days vs. median 226 days; P = 0.011). The delay of relapse with INVEGA® SUSTENNA® was 190 days longer than with oral antipsychotics.

"Ideally, those of us who care for patients would like to help them to be better able to work, interact in meaningful ways with family members and friends, and enjoy everyday activities that people who do not live with mental illness often take for granted," said a trial principal investigator Mohamed Ramadan, M.D., medical director, Mohave Mental Health Clinic, Inc., Bullhead City, Ariz.

No new safety issues were observed during the study. The most commonly observed adverse events (AEs) were consistent with those listed in the current U.S. label, including injection site pain; insomnia; weight increase; akathisia, which is restlessness ranging from a feeling of inner distress to an inability to sit still; and anxiety. Among the trial participants, 53 (23.5%) of those taking INVEGA® SUSTENNA® and 9 (4.1%) of those taking oral antipsychotics reported a treatment-emergent prolactin-related AE. Incidence of specific movement disorders associated with antipsychotics was 23.9% in the INVEGA® SUSTENNA® group and 18.8% in the oral antipsychotic group. A ≥7% increase in weight affected 32.4% of patients in the INVEGA® SUSTENNA® group and 14.4% in the oral antipsychotic group. The study AEs should be evaluated within the context of the trial design and study population.

The study was not powered to compare efficacy of INVEGA® SUSTENNA® with that of individual oral antipsychotics. As with any trial population, results may not be generalized to all persons with schizophrenia.

INVEGA® SUSTENNA® was approved by the U.S. FDA in July 2009 as the first once-monthly atypical long-acting medication to treat schizophrenia. Efficacy initially was established in four short-term studies and one longer-term study in adults.

About Schizophrenia
Schizophrenia is a complex brain disorder that affects three million American adults. 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, brain damage, and environmental factors, such as social stress, isolation and drug use.

About Janssen Pharmaceuticals, Inc.
As a member of the Janssen Pharmaceutical Companies of Johnson & Johnson, Janssen Pharmaceuticals, Inc. is dedicated to addressing and resolving the major unmet medical needs of our time. Driven by our commitment to patients, healthcare professionals, and caregivers, we strive to develop sustainable and integrated healthcare solutions by working in partnership with all stakeholders on the basis of trust and transparency. Our daily work is guided by meeting goals of excellence in quality, innovation, safety, and efficacy in order to advance patient care.

Our company provides medicines for an array of illnesses and disorders in several therapeutic areas. For more information on Janssen Pharmaceuticals, Inc., visit us at www.JanssenPharmaceuticalsInc.com or follow us on Twitter at www.twitter.com/JanssenUS and on YouTube at www.YouTube.com/JanssenUS.

INVEGA® SUSTENNA® (paliperidone palmitate) is indicated for the treatment of schizophrenia. Efficacy was established in four short-term studies and one longer-term study in adults.

IMPORTANT SAFETY INFORMATION FOR INVEGA® SUSTENNA® (paliperidone palmitate)

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS.

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.
- INVEGA® SUSTENNA® is not approved for the treatment of patients with dementia-related psychosis.
- *See full Prescribing Information for Warnings and Precautions (5.1).*

Contraindications: Paliperidone is contraindicated in patients with a known hypersensitivity to either paliperidone, risperidone, or to any components 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. 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.

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

(This press release contains "forward-looking statements," as defined in the Private Securities Litigation Reform Act of 1995, regarding product development. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Pharmaceuticals, Inc. or Johnson & Johnson. Risks and uncertainties include, but are not limited to, challenges and difficulties inherent in new product development, including obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; and trends toward health care cost containment. A further list and description of 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 in its 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 statements as a result of new information or future events or developments.)

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