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HEALTH CANADA APPROVES INVEGA SUSTENNA®* (PALIPERIDONE PALMITATE) FOR THE MAINTENANCE TREATMENT OF SCHIZOAFFECTIVE DISORDER

Approval based on positive data from long-term schizoaffective disorder study measuring ability to delay relapse¹

TORONTO, ON (December 9, 2015) – Janssen Inc. announced today that Health Canada has approved the once-monthly, atypical long-acting antipsychotic INVEGA SUSTENNA® (paliperidone palmitate prolonged-release injectable suspension) for the maintenance treatment of schizoaffective disorder.² Schizoaffective disorder is a serious mental illness that includes a combination of psychotic and mood symptoms.³ Without proper treatment, these symptoms can significantly impact all areas of daily living, including work, school and relationships.⁴

INVEGA SUSTENNA® is the first and only once-monthly medication available in Canada for the maintenance treatment of schizoaffective disorder.⁵ In a controlled clinical trial, treatment with INVEGA SUSTENNA® was found to delay time to relapse compared to placebo. The trial was conducted over a period up to 15 months following a 6-month stabilization period in patients diagnosed with schizoaffective disorder who received treatment either as monotherapy or as adjunctive therapy to mood stabilizers or antidepressants.⁶

INVEGA SUSTENNA® has been available in Canada since 2010 for the treatment of schizophrenia.⁷

“Physicians use multiple medications to address a patient’s schizoaffective disorder symptoms, often with limited success. This can also lead to issues with adherence or drug-to-drug interactions,” says Dr. Pierre Chue, Department of Psychiatry, University of Alberta in Edmonton.** “The approval of an effective monotherapy to treat schizoaffective disorder has the potential to change that approach.”

For additional information, visit www.janssen.com.

About Schizoaffective Disorder

Schizoaffective disorder has features of both schizophrenia and mood disorders, which includes an overlap of psychotic and mood symptoms.⁸ Psychotic symptoms include delusions or hallucinations, and mood symptoms including depression and mania.⁹ The exact cause of schizoaffective disorder is unknown. The disorder is diagnosed via a mental health assessment of symptoms over an extended period of time conducted by a licensed mental health professional.¹⁰ Schizoaffective disorder is a complex condition that is generally treated with a combination of medications.¹¹

About INVEGA SUSTENNA®

INVEGA SUSTENNA® is a long-acting therapy that a health care professional will administer by injection on a monthly basis, thereby alleviating the need to take daily medication for the treatment of schizoaffective disorder. INVEGA SUSTENNA® is indicated for the treatment of schizophrenia and the maintenance treatment of schizoaffective disorder.¹²

The safety profile of INVEGA SUSTENNA® in patients with schizoaffective disorder is generally similar to that observed in patients with schizophrenia.¹³ Adverse events that occurred more frequently during the double-blind period in the INVEGA SUSTENNA® group than the placebo group (a 2 per cent difference or more between groups) were weight increased, nasopharyngitis, headache, hyperprolactinemia, and pyrexia.¹⁴

About Janssen Inc.

Janssen Inc. is one of the Janssen Pharmaceutical Companies of Johnson & Johnson, which are dedicated to addressing and solving some of the most important unmet medical needs in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we bring innovative products, services and solutions to people throughout the world. Please visit www.janssen.com for more information.

Cautions Concerning Forward-Looking Statements

This press release contains “forward-looking statements” as defined in the Private Securities Litigation Reform Act of 1995 regarding a newly approved product. 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 Inc. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainty of commercial success; manufacturing difficulties and delays; product efficacy or safety concerns resulting in product recalls or regulatory action; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; 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.

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***Dr. Pierre Chue was not compensated for any media work. He has been a paid consultant to Janssen Inc.*

References:

¹ INVEGA SUSTENNA® Product Monograph. November 25, 2015

² Ibid.

³ Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. American Psychiatric Association. May 17, 2015

⁴ Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. American Psychiatric Association. May 17, 2015

⁵ INVEGA SUSTENNA® Product Monograph. November 25, 2015

⁶ Ibid.

⁷ Ibid.

⁸ Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. American Psychiatric Association. May 17, 2015

⁹ Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. American Psychiatric Association. May 17, 2015

¹⁰ Mayo Clinic. Schizoaffective Disorder Tests and diagnosis. Available at: <http://www.mayoclinic.org/diseases-conditions/schizoaffective-disorder/basics/tests-diagnosis/con-20029221>. Accessed October 15, 2015.

¹¹ Mayo Clinic. Schizoaffective Disorder Treatment and drugs. Available at: <http://www.mayoclinic.org/diseases-conditions/schizoaffective-disorder/basics/treatment/con-20029221>. Accessed October 15, 2015.

¹² INVEGA SUSTENNA® Product Monograph. November 25, 2015

¹³ Ibid.

¹⁴ Ibid.