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Janssen Receives CHMP Positive Opinion for TREVICTA® (paliperidone palmitate a 3-monthly injection) Recommending Approval in the European Union for the Maintenance Treatment of Schizophrenia

If approved, TREVICTA® will be the first treatment for schizophrenia to be administered four times a year and will provide the longest dosing interval available for an antipsychotic medication in the European Union

BEERSE, BELGIUM, 01 April, 2016 – Janssen-Cilag International NV announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a Positive Opinion recommending marketing authorisation in the European Union for the medicinal product TREVICTA® (paliperidone palmitate a 3-monthly injection) for the maintenance treatment of schizophrenia. If approved, this 3-monthly injection will allow patients to maintain an optimal level of treatment in their blood with fewer administrations, compared to currently available antipsychotic treatments, and therefore may improve outcomes for patients, carers and HCPs.[1] A 1-monthly formulation of paliperidone palmitate (XEPLION®) is approved for the maintenance treatment of schizophrenia in Europe.

“As paliperidone palmitate 3-monthly injection offers the opportunity for fewer (only 4) injections per year, it has the potential to offer eligible patients greater freedom and the opportunity to focus less on taking their medication and more on getting and staying well.” said Dr Andreas Schreiner, European Therapeutic Area Leader, Neuroscience and Pain, Janssen. “The extended dosing interval compared with current treatments may also

reduce the risk of relapse for a patient population in whom adherence to antipsychotic medication can be a major factor in the success of their treatment. We anticipate the EMA's final decision in the coming months and hope that it will allow Janssen to provide patients with a valuable new treatment option for schizophrenia."

The European filing of an Extension Marketing Authorisation Application for paliperidone palmitate, a 3-monthly injection, is based on two Phase 3 studies. The first was a randomised, multi-centre, double-blind, placebo-controlled relapse prevention study in more than 500 patients with schizophrenia.[1] The second study was a randomised, double-blind clinical trial comparing the efficacy and safety of paliperidone palmitate 3-monthly and 1-monthly formulations.[2] Paliperidone palmitate 3-monthly injection was found to be at least as effective in preventing relapse as the paliperidone palmitate 1-monthly formulation and was not associated with any new or unexpected safety signals.[2]

As with all medications, some patients may experience side effects. The most frequently observed adverse drug reactions reported in ≥ 5% of patients in the two double-blind controlled clinical trials of paliperidone palmitate 3-monthly injection were: increased weight, upper respiratory tract infection, anxiety, headache, insomnia and injection site reaction.[1,2]

Based on the CHMP's Positive Opinion, a final authorisation from the European Commission is expected in the coming months. Paliperidone palmitate 3-monthly injection is marketed as INVEGA TRINZA® in the U.S. and received approval from the Food and Drug Administration (FDA) under Priority Review in May 2015.

#ENDS#

About schizophrenia

Schizophrenia is a complex and chronic brain disorder, in which symptoms can be severe and disabling and can affect all aspects of a person's daily life. It affects people from all countries, socio-economic groups and cultures. Its prevalence is similar around the world - almost one person in every 100 will develop schizophrenia before they reach the age of 60, with men slightly more at risk.[3,4]

There is no single cause of schizophrenia. Different factors acting together are thought to contribute to the development of the illness. Both genetic and environmental factors

seem to be important.[5] The symptoms of schizophrenia can include hallucinations, delusions, lack of emotional response, social withdrawal/depression, apathy and a lack of drive or initiative.

Schizophrenia is typically a lifelong condition but there are treatments that can be beneficial. Clinical guidelines recommend that the optimal treatment package is a combination of antipsychotic medication along with psychotherapy, psycho-education and self-help.[6] Effective treatment may allow people with the condition to enjoy a more fulfilling, well rounded life, which may include returning to work or study, independent living and social relationships, which in turn can aid their recovery.

For more information about schizophrenia, as well as helpful resources and interactive tools for those affected by the condition, visit www.schizophrenia24x7.com. This site is sponsored by Janssen Pharmaceutica NV.

About Janssen

The Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology (e.g., multiple myeloma and prostate cancer), immunology (e.g., psoriasis), neuroscience (e.g., schizophrenia, dementia and pain), infectious disease (e.g., HIV/AIDS, hepatitis C and tuberculosis), and cardiovascular and metabolic diseases (e.g., diabetes). Driven by our commitment to patients, we develop sustainable, integrated healthcare solutions by working side-by-side with healthcare stakeholders, based on partnerships of trust and transparency. More information can be found on www.janssen.com/EMEA. Follow us on www.twitter.com/janssenEMEA for our latest news.

Cilag GmbH International; Janssen Biotech, Inc.; and Janssen-Cilag International NV are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development, including potential regulatory approval of a new 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-Cilag International

NV, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; competition, including technological advances, new products and patents attained by competitors; challenges to patents; manufacturing difficulties or delays; product efficacy or safety concerns resulting in product recalls or regulatory action; 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 January 3, 2016, 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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