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European Commission Approves TREVICTA® (paliperidone palmitate a 3-monthly injection), for Maintenance Treatment of Schizophrenia

First treatment for schizophrenia to be administered four times a year

BEERSE, BELGIUM, 31st May 2016 – Janssen-Cilag International NV announced today that the European Commission (EC) has approved the use of TREVICTA® (paliperidone palmitate a 3-monthly injection) for the maintenance treatment of schizophrenia in adult patients. TREVICTA will provide the longest dosing interval available for an antipsychotic medication in the European Union, allowing patients to maintain an optimal level of treatment in their blood with fewer administrations, compared to currently available antipsychotic treatments. This may improve outcomes for patients, carers and healthcare professionals.[1,2] TREVICTA is indicated for the maintenance treatment of schizophrenia in adult patients who are clinically stable on XEPLION®, a 1-monthly paliperidone palmitate product that was approved in 2011 for the maintenance treatment of schizophrenia in the European Union.[1]

"This approval is a big step forward for people living with schizophrenia," said Dr Andreas Schreiner, European Therapeutic Area Leader, Neuroscience and Pain, Janssen. "With fewer administrations per year compared to other approved treatments, TREVICTA can give people with schizophrenia greater freedom to focus on other important aspects of their life and less on their treatment. This new option has the potential to reduce the likelihood of relapse and

progression of the disease. It also helps healthcare professionals ensure the person with schizophrenia can benefit from continuous delivery of medication between administrations."

The marketing authorisation for TREVICTA is based on two Phase 3 studies.[2,3] The first was a randomised, multi-centre, double-blind, placebo-controlled relapse prevention study in more than 500 patients with schizophrenia.[3] The second was a randomised, multi-centre, double-blind study comparing the efficacy and safety of paliperidone palmitate 3-monthly and 1-monthly formulations.[2] TREVICTA 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.[1,2,3]

The decision from the EC follows a Positive Opinion recommending the approval of TREVICTA from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in April 2016.[1] This approval allows for the marketing of TREVICTA in all 28 member states of the European Union as well as the European Economic Area countries (Norway, Iceland and Liechtenstein).

#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.[4,5]

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.[6] The symptoms of schizophrenia can include hallucinations, delusions, lack of emotional response, social withdrawal/depression, apathy and a lack of drive or initiative.[4]

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.[7] 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.[7]

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 the Janssen Pharmaceutical Companies

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com/EMEA. Follow us at www.twitter.com/janssenEMEA.

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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-Cilag International NV and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainty of commercial success; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; manufacturing difficulties and delays; 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 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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References

1. European Medicines Agency, Committee Medicinal Products for Human Use. Summary of opinion: TREVICTA (paliperidone). 1 April 2016. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion/human/004066/WC500204137.pdf (last accessed May 2016).
2. Savitz A *et al.* Efficacy and safety of paliperidone palmitate 3-month formulation for patients with schizophrenia: A randomized, multicenter, double-blind, non-inferiority study. *Int J Neuropsychopharmacol* 2016 (Feb 22). doi: 10.1093 [Epub ahead of print].
3. Berwaerts J *et al*. Efficacy and Safety of the 3-Month Formulation of Paliperidone Palmitate vs Placebo for Relapse Prevention of Schizophrenia: A Randomized Clinical Trial. *JAMA Psych* 2015;72(8):830–9.
4. American Psychiatric Association (APA). Practice guideline for the treatment of patients with schizophrenia. Second edition 2004;42. Available at http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf (last accessed May 2016).
5. Picchioni MM *et al*. Schizophrenia. *BMJ* 2007;335(7610):91–5.
6. Lang U *et al*. Molecular mechanisms of schizophrenia. *Cell Physiol Biochem* 2007;20:687.
7. National Institute for Clinical Excellence: Psychosis and schizophrenia in adults: prevention and management; National Clinical Practice Guidelines Number CG178. Available at https://www.nice.org.uk/guidance/cg178 (last accessed May 2016).