NEWS RELEASE

Janssen Submits European Extension Marketing Authorisation Application for Paliperidone Palmitate Once-Every-Three-Months Formulation

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BEERSE, Belgium, 21 August 2015 - Janssen-Cilag International NV (Janssen) today announced the submission of an Extension Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for paliperidone palmitate once-every-three-months formulation for the treatment of schizophrenia. If approved, it will be the first antipsychotic schizophrenia medication to be administered four times a year.

"This treatment has the potential to offer patients a new dosing schedule, which may result in improved care for many people with schizophrenia," said Dr Andreas Schreiner, European Therapeutic Area Leader, Neuroscience and Pain, Janssen. "We look forward to working with the EMA to make this long-acting therapy available for the treatment of patients with schizophrenia in Europe."

The European filing of paliperidone palmitate once-every-three-months is based on two Phase 3 studies. The first, which was the basis for the U.S. Food and Drug Administration (FDA) submission, is a randomised, multi-centre, double-blind, placebo-controlled relapse prevention study in more than 500 patients with schizophrenia.[1] The second is a randomised, double-blind non-inferiority clinical trial of paliperidone palmitate once-every-three-months and once-monthly formulations.[2] The results will be presented at a scientific congress later this year.

Paliperidone palmitate once-monthly (marketed as XEPLION® in the European Union) is an atypical long-acting injection to treat schizophrenia and is now approved in more than 80 countries. It can help people with schizophrenia to maintain continuous treatment, control their symptoms and avoid relapse.[3-8] This may allow

people with the condition to focus on shaping their future and living their life, which can include returning to work or study, independent living and social relationships. Paliperidone palmitate once-every-three-months formulation, which obtained FDA priority review and is currently approved and launched in the U.S. (and marketed as INVEGA TRINZA®) for patients previously treated with the once-monthly formulation, contains the same active substance as XEPLION but with an extended dosing interval. If approved, it will be marketed as TREVICTA® in Europe.

Schizophrenia is a complex illness in which a person has difficulties in their thought processes, leading to hallucinations, delusions, disordered thinking and unusual speech or behaviour (known as 'psychotic symptoms'). These symptoms mean that people with schizophrenia can find it difficult to interact with others and may withdraw from everyday activities and the outside world. In addition, many people with schizophrenia find it difficult to take their medication continuously, and even short interruptions can lead to a relapse. If approved, this additional once-every-three-months treatment option would offer healthcare professionals the ability to give suitable patients greater independence by enabling them to focus less on taking their medication and more on other aspects of their treatment plan.

END

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Notes to editors

About XEPLION (paliperidone palmitate)[9]

XEPLION is indicated for maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone. In selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, XEPLION may be used without prior stabilisation with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed. For complete EU prescribing information, please visit: **www.ema.europa.eu/docs/en_GB/document_library/EPAR_-**

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About schizophrenia

Schizophrenia 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 and women equally at risk.[10]

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

While schizophrenia is typically a lifelong condition, it is important to remember that there are treatments available that allow people with schizophrenia to get better. Clinical guidelines recommend that the optimal treatment package for people with schizophrenia is a combination of medication along with psychotherapy, psycho-education and self-help.[12]Beyond simply controlling symptoms, 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-Cilag International NV

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people with serious diseases throughout the world. Beyond its innovative medicines, Janssen-Cilag International NV and its affiliates worldwide are at the forefront of developing education and public policy initiatives to ensure patients and their families, caregivers, advocates and health care professionals have access to the latest treatment information, support services and quality care. Please visit **www.janssen-emea.com** for more information. Follow us on **www.twitter.com/JanssenEMEA**.

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. 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: challenges and uncertainties inherent in new product development, including obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; 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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