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BEERSE, Belgium, 4 June 2014: Janssen-Cilag International NV announced today that the European Commission has approved an extension of the oral atypical antipsychotic INVEGA® (paliperidone ER) schizophrenia indication, to include adolescents aged 15 years and older.[1] The decision from the European Commission follows a positive opinion from the Committee for Medicinal Products for Human Use of the European Medicines Agency in April 2014.[2]

"This decision means that INVEGA® becomes an additional treatment choice available to physicians and to young people living with schizophrenia," said Andreas Schreiner, European Therapy Area Lead, Neuroscience and Pain. "We are therefore delighted that the European Commission has approved INVEGA® for the treatment of schizophrenia in adolescents aged 15 years and over."

The approval is based on results from three pivotal Phase 3 studies with INVEGA® in adolescents. Results showed that INVEGA® has a safety and efficacy profile in adolescents similar to that observed in adults with schizophrenia.[3,4,5] In the first, a six-week, randomised, double-blind, placebo controlled study, INVEGA® 3 mg, 6 mg and 12 mg once daily dose strengths resulted in improvements in symptoms of schizophrenia in adolescents.[3]

As an extension to this study, a large two-year open label multicentre Phase 3 study, demonstrated the tolerability and efficacy of flexibly dosed INVEGA®.[4] The data also support the efficacy of INVEGA® in maintaining symptom stability for schizophrenia over the two year treatment period in this patient population.[4]

The third Phase 3 study was a double-blind randomised controlled study which evaluated the efficacy, safety and tolerability of INVEGA® relative to oral aripiprazole[5], another antipsychotic licensed for the treatment of adolescent schizophrenia.[6] The results showed a robust and clinically relevant improvement with INVEGA® in symptom and functional measurements, and demonstrated a tolerability profile similar to that observed in an adult population. [5]

While schizophrenia is a lifelong condition, effective treatments can help people with schizophrenia to live a normal life. Clinical guidelines recommend a combination of medication and psychotherapy, psycho-education and self-help.[7] Beyond simply controlling symptoms, effective treatment means that people living with the condition have a much better chance of returning to, or continuing their work or study and managing independent living and social relationships, which in turn can aid their recovery.

For further information please contact:

Matti Ojanen
Janssen
Phone: +34 91 722 8079
Email: mojanen@its.jnj.com

Joanna Sullivan
Publicis Life Brands Resolute
Phone: +44 (0) 207 071 2017
Email: joanna.sullivan@publicislifebrandsresolute.com

Investor Relations:
Stan Panasewicz
Phone: 1-732-524-2524

Louise Mehrotra
Phone: 1-732-524-6491

About the Phase 3 studies

PALI-PSZ-3001[3]
Patients were randomised to receive either placebo or one of three weight-based, fixed doses of paliperidone ER, once-daily (patients weighting 29 - <51 kg at baseline: 1.5 mg [low], 3 mg [medium] or 6 mg [high]; patients weighing ≥ 51 kg: 1.5 mg [low], 6 mg [medium], 12 mg [high]). The results showed that paliperidone ER was tolerable, and no new safety concerns were observed.

Predictors of response were: paliperidone ER treatment group (medium and high dose combined), shorter duration of illness (≤2 years), and greater illness severity.

PALI-PSZ-3002[4]
Paliperidone ER demonstrated general tolerability for the treatment of schizophrenia in adolescents. Growth and maturation were similar to normal adolescent maturation. Results also showed that efficacy was also maintained over the 2-year treatment period.

PALI-PSZ-3003[5]

A double blind, flexible-dose study (8-week acute, 18-week maintenance) in adolescents (N=226) randomised to paliperidone ER or oral aripiprazole demonstrated that paliperidone ER and aripiprazole had similar treatment effects, as there were no significant differences in primary or secondary efficacy measurements between the two treatment groups. Both drugs showed robust and clinically relevant improvements in symptom and functional measurements, and were generally well tolerated with a safety profile similar to that observed in adults with schizophrenia.

About INVEGA® (paliperidone ER)
INVEGA® (paliperidone ER) is the only antipsychotic currently licensed for the treatment of schizophrenia and schizoaffective disorder.8 It is indicated for the treatment of schizophrenia in adults and adolescents 15 years and older. INVEGA® is indicated for the treatment of psychotic or manic symptoms of schizoaffective disorder in adults. Effect on depressive symptoms has not been demonstrated. To view the updated Summary of Product Characteristics, please visit: http://ec.europa.eu/health/documents/community-register/2014/20140523128792/anx_128792_en.pdf

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.

(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 unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen-Cilag International NV or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in new product development, including obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes in behaviour and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; general industry conditions including trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies. 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 29, 2013, including in Exhibit 99 thereto, and our 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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[1]European Commission. Commission Implementing Decision. Available at: http://ec.europa.eu/health/documents/community-register/2014/20140523128792/dec_128792_en.pdf Last accessed: June 2014

[2]European Medicines Agency. Committee for Medicinal Products for Human Use: Summary of opinion (post authorisation). Available at: www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion/human/000746/WC500165663.pdf Last accessed: June 2014

[3]Singh J *et al*. A Randomized, Double-blind Study of paliperidone extended-release in treatment of acute schizophrenia in adolescents. *Biol Psychiatry* 2011;(70):1179-1187

[4]Savitz A *et al*. A 2-year, safety evaluation of paliperidone extended release in the treatment of adolescents (12 to 17 years of age) with schizophrenia: An open label, flexible dose study. Poster presented at the American Academy of Child and Adolescent Psychiatry Congress, 22-27 October 2013, Florida, USA (PALI-PSZ-3002)

[5]Savitz A *et al*. Efficacy and safety of paliperidone ER in adolescents with schizophrenia: A randomized, multicenter, double-blind, active-controlled, flexible-dose, parallel-group study. Poster presented at the American Academy of Child and Adolescent Psychiatry Congress, 22-27 October 2013, Florida, USA (PALI-PSZ-3003)

[6]Electronic Medicines Compendium, Abilify (aripiprazole) Summary of Product Characteristics (SmPC), available at http://www.medicines.org.uk/emc/medicine/18494/SPC/Abilify+Tablets%2c+Orodispersible+Tablets%2c+Oral+Solution#INDICATIONS Last accessed: June 2014

[7]National Institute for Clinical Excellence. Psychosis and schizophrenia in adults: treatment and management; National Clinical Guideline 178, available at http://www.nice.org.uk/nicemedia/live/14382/66534/66534.pdf Last accessed June 2014

[8]European Commission, Invega (paliperidone ER) Summary of Product Characteristics (SmPC), available at http://ec.europa.eu/health/documents/community-register/2014/20140523128792/anx_128792_en.pdf Last accessed: June 2014