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INVOKANA® (canagliflozin) RECEIVES POSITIVE OPINION RECOMMENDING APPROVAL IN THE EUROPEAN UNION FOR THE TREATMENT OF ADULTS WITH TYPE 2 DIABETES MELLITUS[1]

Beerse, Belgium, September 20, 2013 - Janssen-Cilag International NV (Janssen) announced today that the Committee for Medicinal Products for Human Use (CHMP) has granted a positive opinion recommending approval of INVOKANA® (canagliflozin) in the European Union for the treatment of adults with type 2 diabetes mellitus, to improve glycaemic control.[1] Canagliflozin is an oral, once-daily medication, which belongs to a new class of medications called sodium glucose co-transporter 2 (SGLT2) inhibitors.

David R. Matthews, Professor of Diabetes, Oxford Centre for Diabetes, Endocrinology and Metabolism comments "In Europe, the prevalence of type 2 diabetes continues to be on the rise. Despite there being a number of treatments currently available, many patients are still not able to achieve and maintain long-term control of their blood sugar. Type 2 diabetes is a progressive disease that, if left uncontrolled, can lead to debilitating complications. It is very encouraging that a potential new treatment option, supported by robust clinical data, has been recommended for approval in Europe"

If approved, canagliflozin will provide a new treatment option for the management of adults with type 2 diabetes. It is the first SGLT2 inhibitor to be approved in the United States and, if approved by the European Commission, will provide an additional treatment option for adults with type 2 diabetes.

The kidneys make an important contribution to balancing blood glucose. As glucose is filtered from the blood into the kidneys it is reabsorbed back into the bloodstream. An important carrier responsible for this reabsorption is called sodium glucose co-transporter 2 (SGLT2). Canagliflozin selectively inhibits SGLT2, and, as a result, promotes the loss of glucose via the urine, lowering blood glucose levels in adults with type 2 diabetes.

"This positive opinion from the CHMP represents a major milestone in Johnson & Johnson's longstanding commitment to diabetes. If approved, INVOKANA® will pave the way for Janssen as part of our goal to develop and provide new therapeutic options for adult patients with type 2 diabetes" comments Jane Griffiths, Company Group Chairman, Janssen Europe, Middle-East, Africa.

The Marketing Authorisation Application submission was supported by a comprehensive global Phase 3 clinical programme, which enrolled more than 10,300 patients in nine studies, and is one of the largest late-stage development programmes for an investigational pharmacological product for the treatment of type 2 diabetes submitted to health authorities to date. It assessed the efficacy and tolerability of canagliflozin across the spectrum of adult type 2 diabetes management, in patients who need further glucose control as a single agent (monotherapy), in combination with metformin, and in combination with other glucose-lowering agents, including insulin.

Three studies have compared canagliflozin to current standard treatments; two of which compared canagliflozin to sitagliptin and the other to glimepiride. The Phase 3 programme also included three large studies in special populations; older patients with type 2 diabetes, patients with type 2 diabetes who had moderate renal impairment, and patients with type 2 diabetes who were considered to be at high risk for cardiovascular disease.

The CHMP is the committee responsible for the scientific assessment of products seeking centralised marketing authorisation throughout the European Union. The CHMP's positive opinion recommending the approval of canagliflozin is now referred to the European Commission. Janssen anticipates receiving the regulatory decision from the European Commission in the coming months.

-ENDS-

NOTES TO EDITORS

About Type 2 Diabetes

Type 2 diabetes is a chronic condition that affects the body's ability to metabolize sugar, or glucose, and is characterized by the inability of pancreatic beta cell function to keep up with the body's demand for insulin.[2]

The International Diabetes Federation estimates that in 2011, 366 million people were living with diabetes (type 1 and 2), and the diabetes population is expected to grow to over 550 million in less than 20 years.[2] The World Health Organisation estimates that 90% of the diabetes population have type 2 diabetes.[3]

One in 10 deaths in adults in Europe can be attributed to diabetes (~600,000 people in 2011).[2] If left uncontrolled, type 2 diabetes can lead to serious long-term microvascular and macrovascular complications such as coronary heart disease (leading to heart attack) and stroke, nerve disease leading to amputation, retinopathy resulting in blindness and nephropathy causing end-stage renal disease. Improved glycaemic control has been demonstrated to reduce the onset and progression of these complications.

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, immunology, neuroscience, infectious disease, and cardiovascular and metabolic diseases.

Driven by our commitment to patients, Janssen develops innovative products, services and healthcare solutions to help people throughout the world.

More information can be found at www.janssen-emea.com

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. 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, any of the Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; changes in behavior 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; 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 Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2012. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.

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[1] CHMP opinion: http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion_-_Initial_authorisation/human/002649/WC500150105.pdf

[2] International Diabetes Federation. About Diabetes. Available http://www.idf.org/about-diabetes. Last Accessed: Feb 2013

[3] Definition, diagnosis and classification of diabetes mellitus and its complications. Part 1: Diagnosis and classification of diabetes mellitus. Geneva, World Health Organization, 1999 (WHO/NCD/NCS/99.2)