News Release

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VOKANAMET™ (canagliflozin and metformin fixed dose combination) receives positive CHMP opinion recommending approval in the European Union for the treatment of adults with type 2 diabetes[1]

BEERSE, February 21 2014 – Janssen-Cilag International NV (Janssen) announced today that the Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion, recommending marketing authorisation in the European Union for the medicinal product VOKANAMET™, a fixed-dose therapy combining canagliflozin and immediate release metformin in a single tablet, intended for the treatment of type 2 diabetes mellitus.[1] Canagliflozin is currently available as INVOKANA™ following approval in the European Union in November 2013.

Professor Guntram Schernthaner, Department of Medicine I, Rudolfstiftung Hospital, Austria, comments "If approved, VOKANAMET™ will offer an additional treatment option in the management of type 2 diabetes in Europe. Metformin as a first line therapy for type 2 diabetes has offered real hope for patients to achieve their treatment goals. The potential of combining canagliflozin's mode of action with metformin provides an exciting approach to diabetes management, offering patients the benefits of blood glucose and body weight reduction without increasing the risk for hypoglycaemia."

Canagliflozin is approved in the European Union for the treatment of adult patients with type 2 diabetes mellitus, to improve glycaemic control.[2] It is a member of a new class of drugs known as sodium glucose co-transporter 2 (SGLT2) inhibitors. It plays an important role in the kidney and contributes to controlling blood glucose levels. 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.

Metformin is a first-line pharmacotherapy that can be used alone or with other medications, including insulin, to treat type 2 diabetes. In people with type 2 diabetes, the liver overproduces glucose, which increases blood glucose levels. Metformin lowers blood glucose

levels by decreasing the amount of glucose made by the liver, increasing insulin sensitivity in the muscle and delaying intestinal glucose absorption. [3]

If approved, this canagliflozin and metformin fixed dose combination therapy could provide a new treatment option for the management of adults with type 2 diabetes mellitus and convenience for patients who may benefit from two diabetes medications in one tablet.

Significant portions of the clinical data in this Marketing Authorisation Application (MAA) are derived from the comprehensive global Phase 3 clinical development programme for canagliflozin single agent.

The Phase 3 programme evaluated the safety and efficacy of canagliflozin across the spectrum of type 2 diabetes and included placebo and active comparator controlled studies. Three studies have compared canagliflozin to current standard treatments[4-6], two of which compared canagliflozin to sitagliptin as triple therapy with metformin and sulphonylurea[4,5] and the other to glimepiride as dual therapy with metformin.[6] The Phase 3 programme also included two large studies in special populations[7-9]: patients over 55 with type 2 diabetes[7] and patients with type 2 diabetes who were considered to be at high risk for cardiovascular disease.[9]

Single agent canagliflozin (INVOKANA™) was approved in the US in March 2013, throughout all 28 member countries of the European Union in November 2013 and in a growing number of countries around the world.

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 the fixed dose combination of canagliflozin and metformin is now referred to the European Commission. Janssen anticipates receiving the regulatory decision from the European Commission in the coming months.

Janssen and its affiliates have rights to canagliflozin through a license agreement with Mitsubishi Tanabe Pharma Corporation. Janssen and its affiliates have marketing rights in North America, South America, Europe, the Middle East, Africa, Australia, New Zealand and parts of Asia.

About Type 2 Diabetes

Type 2 diabetes is a chronic condition that affects the body's ability to metabolise sugar, or glucose, and is characterised by the inability of pancreatic beta cell function to keep up with the body's demand for insulin.[10]

The International Diabetes Federation estimates that, in 2013, 382 million people globally were living with diabetes (type 1 and 2) in 2013, and the diabetes population is expected to grow to over 592 million by 2035.[11] The World Health Organisation estimates that 90% of the diabetes population have type 2 diabetes.[12]

If left uncontrolled, type 2 diabetes can lead to serious long-term microvascular and macrovascular complications. Improved glycemic 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, we develop 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, including statements concerning expectations for VOKANAMET. 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 other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, 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 to governmental laws and regulations and domestic and foreign 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 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 or Johnson & Johnson undertakes to update any forward-looking statements as a result of new information or future events or developments.

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1. EMA Summary of Opinion: VOKANAMET. http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion_-_Initial_authorisation/human/002656/WC500161964.pdf
2. INVOKANA SmPC. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/002649/WC500156455.pdf. Last accessed: January 2014
3. Glucophage Summary of Product Characteristics last updated on the eMC: 12/10/2010 http://www.medicines.org.uk/emc/medicine/1043. Last accessed: January 2014
4. Lavalle-González FJ et al. Efficacy and safety of canagliflozin compared with placebo and sitagliptin in patients with type 2 diabetes on background metformin monotherapy: a randomised trial. Diabetologia. 2013;56(12):2582-92
5. Schernthaner G et al. Canagliflozin compared with sitagliptin for patients with type 2 diabetes who do not have adequate glycemic control with metformin plus sulfonylurea: a 52-week randomized trial. Diabetes Care. 2013; 36(9):2508-15

6. Cefalu WT et al. Efficacy and safety of canagliflozin versus glimepiride in patients with type 2 diabetes inadequately controlled with metformin (CANTATA-SU): 52 week results from a randomised, double-blind, phase 3 non-inferiority trial. Lancet. 2013; 382(9896):941-50.
7. Bode B et al. Efficacy and safety of canagliflozin treatment in older subjects with type 2 diabetes mellitus: a randomized trial. Hosp Pract. 2013;41(2):72-84.
8. Yale JF et al. Efficacy and safety of canagliflozin in subjects with type 2 diabetes and chronic kidney disease. Diabetes Obes Metab. 2013;15(5):463-73.
9. Neal B, Perkovic V, *et al*. (2013). Rationale, design, and baseline characteristics of the Canagliflozin Cardiovascular Assessment Study (CANVAS)—A randomized placebo-controlled trial. American Heart Journal; 166(2): 217-223
10. International Diabetes Federation. About Diabetes. Available http://www.idf.org/about-diabetes. Last Accessed: January 2014
11. International Diabetes Federation. IDF Diabetes Atlas, 6th edn. Brussels, Belgium: International Diabetes Federation, 2013. http://www.idf.org/diabetesatlas. Last accessed January 2014
12. 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)