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INVOKANA™ (canagliflozin) APPROVED IN THE EUROPEAN UNION FOR TREATMENT OF ADULTS WITH TYPE 2 DIABETES [1]

Beerse, Belgium, November 22, 2013 - Janssen-Cilag International NV (Janssen) announced today that the European Commission (EC) has approved 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.

The decision from the EC follows a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending the approval of canagliflozin in September 2013. Canagliflozin is indicated in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control;

- as monotherapy, when diet and exercise alone do not provide adequate glycaemic control in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications
- or as add-on therapy with other anti-hyperglycaemic medicinal products including insulin, when these together with diet and exercise, do not provide adequate glycaemic control.

Professor Guntram Schernthaner, Department of Medicine I, Rudolfstiftung Hospital, Austria, comments "For patients with type 2 diabetes, managing blood sugar levels is a daily struggle. Nearly half of adults suffering from the disease fail to achieve or maintain adequate levels of glucose, which can lead to potentially life-threatening complications. For the growing number of patients with type 2 diabetes in Europe, the approval of a new additional treatment option is very welcome".

The kidneys make an important contribution in 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. Large scale studies have demonstrated that due to the increased urinary loss of glucose, canagliflozin is also associated with reductions in both systolic blood pressure and body weight.[2]

"We are delighted that INVOKANA ™ has been approved for use in Europe, as it presents another innovative treatment option for patients with type 2 diabetes, helping them manage this progressive disease. The approval of canagliflozin also reinforces Janssen's commitment to addressing the unmet needs in the treatment and management of type 2 diabetes," comments Jane Griffiths, Company Group Chairman, Janssen Europe, Middle-East, Africa.

The approval by the EC was based on a comprehensive global Phase 3 clinical trial programme, which enrolled 10,285 patients in nine studies[2-11], 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.

Three studies have compared canagliflozin to current standard treatments[3-5]; two of which compared canagliflozin to sitagliptin[3,4] and the other to glimepiride.[5] The Phase 3 programme also included three large studies in special populations[6-8]: patients over 55 with type 2 diabetes[6], patients with type 2 diabetes who had moderate renal impairment[7], and patients with type 2 diabetes who were considered to be at high risk for cardiovascular disease.[8]

Results from the programme showed that both the 100 mg and the 300 mg doses of canagliflozin improved glycaemic control, compared to baseline. A secondary study endpoint showed that there was body weight reduction in the canagliflozin groups compared to those on placebo. Phase 3 results showed that canagliflozin was generally well-tolerated. Adverse drug reactions due to SGLT2 inhibition and also associated with canagliflozin included genital mycotic infections, urinary tract infections (UTIs), osmotic diuresis (such as urinary frequency, thirst or constipation), reduced intravascular volume (such as postural dizziness). Canagliflozin was also associated with a low incidence of rash or urticaria. The frequency of hypoglycaemia was low when canagliflozin was used as a monotherapy, or as an add-on to metformin.[2]

Canagliflozin was first approved by the U.S. Food and Drug Administration (FDA) in March 2013 and recently also in Australia.

-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.[12]

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.[12] The World Health Organisation estimates that 90% of the diabetes population have type 2 diabetes.[13]

One in 10 deaths in adults in Europe can be attributed to diabetes (~600,000 people in 2011).[12] 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

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