

PRESS RELEASE

15th April, 2015

Janssen India Launches INVOKANA[®] To Address Growing Diabetes Pandemic

Mumbai, April 15 2015 – Janssen, one of the Janssen pharmaceutical companies of Johnson & Johnson, announced today the launch of INVOKANA[®] (canagliflozin), a highly differentiated and important new treatment option for the estimated 67 million people² suffering from diabetes in India, which has the world's second largest diabetes population.

Taken orally once a day, INVOKANA[®] belongs to a new class of medications called sodium glucose (sugar) co-transporter 2 (SGLT2) inhibitors which work in a completely different way to other classes of type 2 diabetes medications. INVOKANA[®] has been shown to reduce glucose levels in adults who have previously not been able to achieve adequate control through diet and lifestyle measures, or through treatment with other blood sugar-lowering medicines.¹

Type 2 diabetes is a serious chronic disease that causes glucose levels in the blood to become too high. In 2014, an estimated 4.9 million worldwide deaths were directly caused by diabetes² and associated conditions such as cardiovascular disease.

Diabetes was the cause of more than one million deaths² in India in 2014, with the prevalence of diabetes reaching a pandemic proportion in the country due to rapid lifestyle transitions and a narrowing in the urban-rural divide in living conditions.⁵ Glycemic control (blood sugar control) in India can often be poor and this has resulted in high prevalence of microvascular complications. People living with diabetes in India face a constant challenge to manage their blood glucose levels, keep their blood pressure under control and to maintain an ideal weight.

Type 2 Diabetes mellitus and its complications are causes of major healthcare burden in India. Newer therapies are needed to combat this progressive disease," commented Dr. Ambrish Mithal, Chairman, HOD, Division of Endocrinology and Diabetes, Medanta, the Medicity. "SGLT2 Inhibitors like Canagliflozin are important new options in type 2 diabetes treatment which act by novel insulin independent mechanism. Canagliflozin has shown good results in controlling the blood sugar without increasing risks of hypoglycemia (low blood sugar) and additional advantages like weight loss in clinical trials".

INVOKANA[®] and other SGLT2 inhibitors work differently from other classes of type 2 diabetes treatments by blocking the reabsorption of glucose in the kidneys. The result is that more glucose is excreted in the urine thereby reducing levels of blood glucose – a major goal of diabetes treatment. The efficacy of INVOKANA[®] has been studied in trials involving over 10,000 patients, making it one of the largest development programmes for type 2 diabetes in the world. The trials, which included significant number of subjects from India (1,038), showed INVOKANA[®] to increase the loss of glucose through urine, helping restore normo-glycemia with low hypoglycemia risk.



A study by the Indian Council of Medical Research-India Diabetes (ICMR-INDIAB) shows that awareness level of diabetes in India is low⁶. The Chennai Urban Rural Epidemiology Study (CURES) reported that up to 25% of people in Chennai were not aware of diabetes and its implications.⁷ The estimated annual cost for diabetes care would be approximately INR 18000 crores.⁸

Clinical studies showed INVOKANA[®] to be generally well tolerated. The most common adverse events with it are genital fungal infections such as candidiasis, urinary tract infections and increased urination.¹ These specific adverse events were generally mild to moderate in intensity and infrequently led to discontinuation in Phase III studies.¹

Furthermore, there is a low risk of hypoglycaemia (when blood glucose levels fall dangerously low) associated with canagliflozin treatment when it is used as monotherapy or with metformin. Evidence to date suggests the use of INVOKANA[®] is not associated with an increase in cardiovascular risk.¹

“The launch of INVOKANA[®] in India is an exciting milestone for Janssen,” commented Sanjiv Navangul, Managing Director, Janssen India. “With the relentless increase in the number of people with type 2 diabetes in the country, there is an ongoing need for additional treatment options.”

“Overweight and obesity are important co-morbidities in type 2 diabetes and further increase the risk of vascular complications while affecting the quality of life. This is a major unmet medical need in diabetes management,” says Dr. Vikram Singh, Vice President-Medical Affairs and Pharmacovigilance-Janssen India. “In addition to its glycemic efficacy, INVOKANA[®] also helps patients with type 2 diabetes in reducing the body weight.”

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Notes to Editors

About Type 2 Diabetes

Type 2 diabetes is a serious chronic disease characterized by high levels of sugar (glucose) in the blood. This is caused either by insulin deficiency (where the beta-cells in the pancreas do not produce enough insulin), and/or by insulin resistance (when the body cannot effectively use the insulin it produces).

Diabetes mellitus is one of the most common chronic diseases across the world and number of diabetic patients is on rise. In 2014 there were 387 million people with diabetes globally, this is expected to rise by up to 592 million by 2030.² Most people with diabetes live in low and middle-income countries like India, and these countries are likely to see the greatest increase over the next 19 years. The latest diabetes atlas reported that there are about 67 million people in India with diabetes mellitus and about 35.5 million people with undiagnosed diabetes in India.² In addition, diabetes is the biggest single cause of amputation, stroke, blindness and end stage kidney failure.³

About INVOKANA®

INVOKANA® is licensed for adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control; INVOKANA® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus as monotherapy and combination therapy

INVOKANA® has been studied as a single agent (monotherapy), in combination with metformin, and in combination with other glucose-lowering agents, including insulin, in patients who need further glucose control. In the Phase III studies, INVOKANA® demonstrated clinically and statistically significant ($p < 0.001$) results relative to placebo in glycaemic control, including the percentage of patients achieving HbA1c $< 7\%$.¹ In addition, both non-inferior (INVOKANA® 100mg) and statistically superior (INVOKANA® 300mg) reductions in HbA1c were achieved versus both glimepiride and sitagliptin.^{9,10,11}

Side Effects

Clinical studies showed INVOKANA® to be generally well tolerated. The most common adverse events with INVOKANA® are genital fungal infections such as thrush, urinary tract infections and increased urination.¹ These specific adverse events were generally mild to moderate in intensity and infrequently led to discontinuation in Phase III studies.¹

Furthermore, there is a low risk of hypoglycaemia associated with treatment with INVOKANA® (when blood glucose levels fall dangerously low) when it is used as monotherapy or with metformin and evidence to date suggests the use of INVOKANA® is not associated with an increase in cardiovascular risk.¹

This medicinal product is subject to additional monitoring and it is important to report any side effects you may get. For complete prescribing information, please contact: Johnson & Johnson Private Limited, Arena Space, Behind Majas Depot, Off J.V. Link Road, Jogeshwari (E), Mumbai 400060

About Janssen India

Janssen, the pharmaceutical division of Johnson & Johnson, is dedicated to addressing and solving some of the most important unmet medical needs of our time in India, in oncology, immunology, neurosciences & analgesia, dermatology, infectious diseases and metabolic diseases in India. Driven by a strong commitment to the health and well-being of patients, Janssen India brings innovative products, services and solutions to people throughout the world. Janssen recognizes the impact of serious conditions on people's lives, and aims to empower people through disease awareness, education and access to quality care in these six therapeutic areas.

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