

PRESS RELEASE

24th February, 2014

UK launch of once-daily tablet from Janssen provides new option to improve blood glucose control for thousands of people with Type 2 diabetes¹

London, 24 February 2014 – Janssen announced today the launch of INVOKANA[®] ▼ (canagliflozin) in the UK, a new Type 2 diabetes treatment shown to reduce blood sugar levels in people for whom diet and lifestyle measures or treatment with other blood sugar-lowering medicines, do not provide adequate control.¹

In parallel with today's launch, canagliflozin has also received a preliminary positive recommendation from the National Institute for Health and Care Excellence (NICE), as a treatment option for adults with Type 2 diabetes.²

Type 2 diabetes is a serious chronic disease that causes sugar (glucose) levels in the blood to become too high. It is associated with around 24,000 excess deaths each year mainly from cardiovascular disease and is the biggest single cause of amputation, stroke, blindness and end stage kidney failure.³ Crucially, its prevalence is increasing throughout the UK, with an estimated 3.2 million people currently living with diabetes – 90 per cent of whom have Type 2 diabetes.^{4,5}

"Every year, we are seeing a growing number of people with Type 2 diabetes which can have the extremely serious consequences of heart attack, stroke, blindness, kidney failure and amputations," commented Professor Anthony Barnett, Emeritus Professor of Medicine, University of Birmingham and Consultant Physician Heart of England NHS Foundation Trust Birmingham. "Canagliflozin, which can offer patients significant reductions in blood sugar levels whilst not increasing risks of hypoglycaemia (low blood sugars), represents an important new option in the management of what is now a major UK epidemic."

Canagliflozin is an oral, once-daily tablet, belonging to a new class of medicines called sodium glucose co-transporter 2 (SGLT2) inhibitors. It works differently to the most commonly used 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.¹

The efficacy of canagliflozin has been studied in trials involving over 10,000 people with Type 2 diabetes in all lines of treatment,¹ making it one of the largest development programmes for Type 2 diabetes in the world.

According to the National Diabetes Audit, more than a third (34.2%) of people diagnosed with Type 2 diabetes in England and Wales are currently failing to achieve recommended blood glucose levels.

The NHS currently spends about £10 billion a year on treating diabetes, 80 per cent of which goes into managing avoidable complications.³ By helping people with Type 2 diabetes improve control of blood glucose levels, their risk of developing potentially life-threatening complications can be significantly reduced, which in turn could save the NHS millions of pounds.^{3,5}

Side Effects

Clinical studies showed canagliflozin to be generally well tolerated. The most common adverse events with canagliflozin 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 (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 canagliflozin is not associated with an increase in cardiovascular risk.¹

“The launch of canagliflozin in the UK is an exciting milestone for Janssen,” commented Dr Peter Barnes, Medical Director at Janssen UK. “With the relentless increase in the number of people with Type 2 diabetes, there is an ongoing need for additional treatment options. Not only does canagliflozin provide a new once a day oral treatment to help control blood glucose levels, it offers real value to the NHS.”

-End-

For more information, please contact:

Media Enquiries:

Emily Bone

01494 567 567

ebone1@its.jnj.com

Notes to Editors

About Type 2 diabetes

Type 2 diabetes is a serious chronic disease characterised by high levels of sugar (glucose) in the blood.⁴ 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).⁶

An estimated 3.2 million people are affected by diabetes in the UK, with 90 per cent of these individuals (approximately 2.9 million) diagnosed with Type 2 diabetes.^{4,5} By 2025, it is estimated that 5 million people will have diabetes, most of whom will have Type 2 diabetes.³

More than one third of adults with Type 2 diabetes do not achieve recommended levels of glucose control.⁷ If left uncontrolled, Type 2 diabetes can lead to serious complications including heart disease, stroke, blindness, kidney disease and amputations.⁵ Improved glycaemic control has been demonstrated to reduce the onset and progression of these complications. It is estimated that approximately £10 billion is spent by the NHS on diabetes, which is ten per cent of the NHS budget.³ A substantial proportion of NHS spending (80%) goes into managing these avoidable complications.³

About canagliflozin

Canagliflozin is licensed for 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 glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control¹

Canagliflozin 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, canagliflozin 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 (canagliflozin 100mg) and statistically superior (canagliflozin 300mg) reductions in HbA1c were achieved versus both glimepiride and sitagliptin.^{8,9,10}

Side Effects

Clinical studies showed canagliflozin to be generally well tolerated. The most common adverse events with canagliflozin 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 canagliflozin (when blood glucose levels fall dangerously low) when it is used as monotherapy or with metformin and evidence to date suggests the use of canagliflozin is not associated with an increase in cardiovascular risk.¹

For more details, please refer to the Summary of Product Characteristics.¹

The National Institute for Health and Care Excellence (NICE) is currently reviewing canagliflozin as part of the Single Technology Appraisal (STA) process.² On 24th February 2014, NICE published preliminary guidance which recommends the use of INVOKANA[®] (canagliflozin) as a treatment for adults with Type 2 diabetes.²

The wording of this preliminary guidance is as follows:²

- 1.1 Canagliflozin in a dual therapy regimen in combination with metformin is recommended as an option for treating Type 2 diabetes, only if:
 - the person is at significant risk of hypoglycaemia or its consequences or a sulfonylurea is contraindicated or not tolerated.
- 1.2 Canagliflozin in a triple therapy regimen in combination with metformin and a sulfonylurea is recommended as an option for treating Type 2 diabetes.
- 1.3 Canagliflozin in combination with insulin with or without other antidiabetic drugs is recommended as an option for treating Type 2 diabetes.

▼ This medicinal product is subject to additional monitoring and it is important to report any side effects you may get. You can see in the leaflet of your medicine how to report side effects.

About Janssen

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 bring innovative products, services and solutions to people throughout the world. Janssen-Cilag Limited is the legal entity for Janssen in the UK. Please visit www.janssen.co.uk for more information.

References

¹ INVOKANA (canagliflozin) SmPC:

<https://www.medicines.org.uk/emc/searchresults.aspx?term=canagliflozin&searchtype=QuickSearch> Last accessed February 2014

² NICE. Canagliflozin ACD. Available at: <http://guidance.nice.org.uk/tag/349/consultation/latest> Last accessed February 2014

³ Diabetes UK: 'State of the Nation 2012' report. Available at: <http://www.diabetes.org.uk/Professionals/Publications-reports-and-resources/Reports-statistics-and-case-studies/Reports/State-of-the-Nation-2012/> Last accessed February 2014

⁴ Diabetes UK: What is diabetes? Available at: http://www.diabetes.org.uk/Guide-to-diabetes/Introduction-to-diabetes/What_is_diabetes/ Last accessed February 2014

⁵ Diabetes UK: 'Diabetes in the UK 2012' Key statistics on diabetes report. Available at:

<http://www.diabetes.org.uk/Professionals/Publications-reports-and-resources/Reports-statistics-and-case-studies/Reports/Diabetes-in-the-UK-2012/> Last accessed February 2014

⁶ American Diabetes Association. *Diabetes Care* 2012 January; **32**(Supplement 1): S64–S71. Available at:

http://care.diabetesjournals.org/content/35/Supplement_1.toc Last accessed February 2014

⁷ National Diabetes Audit 2011-2012. Available at: www.hscic.gov.uk/catalogue/PUB12421/nati-diab-audi-11-12-care-proc-rep.pdf Last accessed February 2014

⁸ Lavalley-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

⁹ 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

¹⁰ 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