Swissmedic reviewing licence extension for the SGLT2 inhibitor Invokana® (canagliflozin) in fast-track procedure

- Swissmedic is currently conducting a fast-track review of an application to extend marketing authorisation for Invokana® (canagliflozin) to the treatment of patients with type 2 diabetes mellitus (T2DM) and chronic kidney disease (CKD).
- The CREDENCE renal outcomes study, which was stopped early in July 2018 owing to positive efficacy findings, served as the basis for the extension submission to Swissmedic.
- If the extension is approved, canagliflozin will be the first therapy in nearly 20 years indicated to reduce the risk of end-stage renal disease (ESRD) when added to the current standard of care for this group of T2DM patients.
- As partner to Janssen Pharmaceutica NV, Mundipharma has exclusive distribution rights for canagliflozin in various countries within Europe, which includes Switzerland.

Cambridge, 10th October 2019 – Mundipharma welcomes the news that Swissmedic (the Swiss Agency for Therapeutic Products; the surveillance authority for medicines and medical devices in Switzerland) is conducting a fast-track review of Mundipharma Switzerland’s application to extend marketing authorisation for the SGLT2 inhibitor canagliflozin as an adjunct to the standard of care in adults with type 2 diabetes mellitus (T2DM) and stage 2 or stage 3 chronic kidney disease (CKD) and albuminuria. The submission is based on data from the Phase III CREDENCE study, which evaluated the efficacy and safety of canagliflozin versus placebo in this high-risk patient population when used in addition to the current standard of care.¹

“Chronic kidney disease is a serious complication of type 2 diabetes, which can increase patients’ risk of developing end-stage renal disease and may reduce their life expectancy by several years.” said Dr Vinicius Gomes de Lima, European Medical Affairs Lead, Mundipharma. “If approved, this licence extension in Switzerland would be the first significant step forward in nearly two decades, to help reduce the associated burden of chronic kidney disease and improve quality of life for these patients.”

Approximately 40% of T2DM patients develop diabetic kidney disease (DKD)². This has a major impact on their physical and emotional health as well as their quality of life, and amplifies their risk of additional
diabetes complications such as cardiovascular disease, infections, fatigue, depression, adverse drug reactions and premature death.\textsuperscript{3} Data from the Swiss dialysis registry show that around one third of dialysis patients have T2DM and that approximately 17\% of patients have diabetic nephropathy as an underlying kidney disease.\textsuperscript{4} There is therefore a great need for new therapies that cater for the kidney-related complications of T2DM.\textsuperscript{2}

Canagliflozin has been authorised in Switzerland since 2014 for the treatment of adults with insufficiently controlled T2DM as an adjunct to diet and exercise, either as monotherapy or in addition to other blood sugar-reducing medicinal products.\textsuperscript{5}

In Europe, canagliflozin is currently indicated for the treatment of adults with insufficiently controlled T2DM as an adjunct to diet and exercise. The initiation dose is 100mg once daily in adults with an eGFR of $\geq 60$ mL/min/1.73 m$^2$ and can be increased to 300mg once daily orally if tighter glycaemic control is needed. Canagliflozin should not be initiated if eGFR is $< 60$ mL/min/1.73 m$^2$. In patients tolerating canagliflozin whose eGFR falls persistently below 60 mL/min/1.73 m$^2$ the dose should be adjusted to or maintained at 100mg once daily. Canagliflozin should be stopped if eGFR falls persistently below 45 mL/min/1.73 m$^2$.\textsuperscript{6}

Canagliflozin has been approved in the European Union since 2013 and was approved for use in Switzerland in 2014.

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Notes to the editors:

About Invokana (canagliflozin)\textsuperscript{6}

Canagliflozin is an oral, once-daily medication that belongs to a class of medications called sodium glucose co-transporter 2 (SGLT2) inhibitors. SGLT2 inhibitors work by inhibiting SGLT2 co-transporter, which promotes the excretion of glucose via the urine, and thus helps lowering blood glucose levels in adults with T2DM.

Canagliflozin was approved in the European Union by the European Commission in November 2013. It is indicated for the treatment of adults with insufficiently controlled T2DM as an adjunct to diet and
exercise, as monotherapy when metformin is considered inappropriate due to intolerance or contra-indications and in addition to other medicinal products for the treatment of diabetes. Approval was based on a comprehensive global Phase III clinical trial programme.

Swissmedic authorised canagliflozin for marketing in Switzerland in 2014, where it is indicated for the treatment of adults with insufficiently controlled T2DM as an adjunct to diet and exercise and in addition to other blood sugar-lowering medicinal products.

About the CREDENCE Clinical Trial\(^1\)

The CREDENCE (Canagliflozin and Renal Events in Diabetes with Established Nephropathy Clinical Evaluation) study was the first dedicated and fully recruited renal outcome trial evaluating renal and cardiovascular outcomes in people with type 2 diabetes mellitus (T2DM) and chronic kidney disease (CKD) with a sodium glucose co-transporter 2 (SGLT2) inhibitor. It was a phase III randomised, double-blind, event-driven, placebo-controlled, parallel-group, two-arm multicentre study of the effects of canagliflozin on renal and cardiovascular outcomes in subjects with T2DM and CKD. In particular, it compared the efficacy and safety of canagliflozin versus placebo in preventing clinically important kidney and cardiovascular outcomes in patients with T2DM and CKD when used in addition to standard of care, including a maximum tolerated daily dose of an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB). The study was stopped early in July 2018 owing to positive efficacy findings.

About the Mundipharma network

Mundipharma is a global network of privately-owned independent associated companies whose purpose is to move medicine forward. With a high performing and learning organisation that strives for innovation and commercial excellence through partnerships, we successfully transformed and diversified our European portfolio of medicines to create value for patients, payers and wider healthcare systems across important therapeutic areas such as Diabetes, Respiratory, Oncology, Pain and Biosimilars.

Invokana\(^\circledast\) is a registered trademark of Janssen and its group companies.
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**References:**