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EMA issues positive opinion to Janssen's INVOKANA and VOKANAMET

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The positive opinion will now be reviewed by the European Commission, which has the authority to grant approval of the updated label.

The Janssen Pharmaceutical Companies of Johnson & Johnson has announced that the Committee for Medicinal Products for Human Use (CHMP), of the European Medicines Agency (EMA), has issued a positive opinion to update the INVOKANA (canagliflozin) and VOKANAMET (canagliflozin and metformin) labeling including changes to the indication statement for the treatment of adults with insufficiently controlled type 2 diabetes mellitus (T2DM) as an adjunct to diet and exercise. The recommended product information now includes data on the reduction in major adverse cardiovascular (CV) events (cardiovascular mortality, non-fatal myocardial infarction, or non-fatal stroke) in patients with type 2 diabetes mellitus (T2DM) who had either a history of CV disease or at least two CV risk factors, in addition to the existing study results on improving glycemic control.

The CHMP's positive opinion will now be reviewed by the European Commission, which has the authority to grant approval of the updated label.

"We are pleased with the CHMP's decision to recommend a label update for canagliflozin to include the results of the CANVAS Program. Both improvement in glycemic control and reduction of CV morbidity and mortality are important in T2DM patients. If approved by the European Commission, this will provide a more comprehensive overview of the effects of canagliflozin, and further assist clinicians in making informed treatment decisions that are most appropriate for their patients," said Dr. Jose Antonio Buron, Vice-President Medical Affairs EMEA, Janssen-Cilag Farmacêutica, Lda.

The Type II variation application is based on the results of the CANVAS Program, the largest completed CV outcomes trial to date for an SGLT2 inhibitor. The study, which included over 10,000 patients started in 2009, met its primary endpoint and showed canagliflozin significantly reduced the combined risk of CV death, myocardial infarction and non-fatal stroke, versus placebo in adult patients with T2DM who had either a history of CV disease or at least two CV risk factors.

Canagliflozin also significantly lowered the risk of hospitalization for heart failure and demonstrated improved renal outcomes.

Adverse events reported in the CANVAS Program were generally consistent with the known safety profile of canagliflozin. However, the study found that, in patients with T2DM who had established CV disease or at least two risk factors for CV disease, canagliflozin was associated with an approximately 2-fold increased risk of lower limb amputation with the rate of amputation over standard of care being 0.63/100 patient years for canagliflozin versus 0.34/100 patient years for placebo which corresponds to an additional risk of 0.29/100 patient years. The risk of amputations across the class has previously been investigated by the EMA, and this is reflected in a warning in the labeling of SGLT2 inhibitors.

Canagliflozin was approved in the European Union by the European Commission in November 2013 and is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus. Approval was based on a comprehensive global Phase 3 clinical trial programme.

Janssen has a partnership with Mundipharma, who is the exclusive distributor for both INVOKANA and VOKANAMET in countries in the European Economic Area (EEA) and Switzerland where the products currently have pricing and reimbursement status. Mundipharma has exclusive rights to promote, distribute, and sell both products through its network of independent associated companies. This is with the exception of Spain, where the product is co-promoted by both Janssen and Mundipharma.