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Janssen unique diabetes drug gets FDA nod

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Singapore: Janssen Pharmaceuticals received approval for Invokana (canagliflozin) for the treatment of adults with type 2 diabetes from the US FDA. The drug is the first in a new class of medications called sodium glucose co-transporter 2 (SGLT2) inhibitors to be approved in the US. It is also the only oral, once-daily medication available in the US that offers improved glycemic control while also showing reduced body weight and systolic blood pressure in clinical trials.

Invokana works differently than other currently-available medicines because it reduces blood glucose by acting on the kidneys as a 'glucuretic,' increasing the loss of glucose in the urine. What has historically been viewed as a sign of diabetes, glucose in the urine, may also reflect the efficacy of a new and unique approach to treatment. An important carrier responsible for reabsorption of glucose in the kidneys, is sodium glucose co-transporter 2 (SGLT2). Invokana selectively inhibits SGLT2, and as a result promotes the loss of glucose in the urine, lowering blood glucose levels in adults with type 2 diabetes.

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. Results from the phase III studies showed that the drug was generally well tolerated. The most common adverse events with Invokana are genital mycotic (fungal) infections, urinary tract infections, and increased urination. These specific adverse events were generally mild to moderate in intensity and infrequently led to discontinuation in phase III studies.

Overall the rate of discontinuation due to adverse events was 4.3 percent for the Invokana starting dose of 100 milligrams (mg), 3.6 percent for Invokana 300 mg and 3.1 percent versus competitors. The new drug application for Invokana was based on a comprehensive global phase III clinical program, which enrolled 10,285 patients in nine studies and is one of the largest clinical programs in type 2 diabetes submitted to health authorities to date. Janssen and its affiliates have rights to the drug through a license agreement with Mitsubishi Tanabe Pharma.

Dr Kirk Ways, development head, cardiovascular, metabolism and compound development team leader, canagliflozin, Janssen Research & Development, said that, "We are delighted with the approval of Invokana because it provides a much-needed, new treatment option to help adults with type 2 diabetes and their physicians manage this disease."