

FDA OKs J&J's Invokana for heart conditions

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Singapore – The Janssen Pharmaceutical Companies of Johnson & Johnson announced that the U.S. Food and Drug Administration (FDA) has approved INVOKANA (canagliflozin) to reduce the risk of major adverse cardiovascular (CV) events, including heart attack, stroke or death due to a cardiovascular cause in adults with type 2 diabetes (T2D) who have established CV disease. INVOKANA is the first and only oral diabetes treatment approved with this indication.

“This FDA approval makes INVOKANA the only oral type 2 diabetes treatment indicated to reduce the risk of heart attack, stroke or CV death. It is an important step forward for patients and the physicians who treat them”, said James List, M.D., Ph.D., Global Therapeutic Area Head, Cardiovascular & Metabolism, Janssen Research & Development, LLC. “Not only does INVOKANA enable patients to control their diabetes symptoms by lowering their A1C levels, but it now also helps protect them from potentially devastating cardiovascular events.”

This FDA approval builds on recent consensus reports from the American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists (AACE) that support the use of INVOKANA across a broad range of patients. For patients with T2D and clinical CV disease, the ADA recommends medication management with SGLT2 (sodium-glucose cotransporter-2) inhibitors that specifically have a proven cardiovascular benefit. AACE also notes that for appropriate patients, INVOKANA has been shown to reduce major adverse CV events.

This new indication also applies to the fixed-dose combinations of INVOKAMET (canagliflozin/metformin HCl) tablets and INVOKAMET XR (canagliflozin/metformin HCl extended-release) tablets.