Treatment with the anti-diabetic drug alogliptin does not increase CV risk in patients with ACS

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Patients with type 2 diabetes and high cardiovascular risk due to recent acute coronary syndromes had similar rates of cardiovascular events when treated with the anti-diabetic agent alogliptin compared to placebo according to results of the Examination of Cardiovascular Outcomes with Alogliptin versus Standard of Care (EXAMINE) trial presented at the European Society of Cardiology Congress.

"Compared with placebo, treatment with alogliptin resulted in similar rates of the primary endpoint, which was a composite of cardiovascular death, myocardial infarction, and stroke ," said the chair of the study's steering committee William B. White, MD, from the University of Connecticut School of Medicine in Farmington, Connecticut, USA.

"The findings could guide clinicians to choose among the many anti-diabetic agents available when treating patients with type 2 diabetes and very high cardiovascular risk," he suggested.

EXAMINE, designed as a non-inferiority trial, was undertaken to satisfy U.S. Food and Drug Administration requirements that new diabetes drugs be subjected to studies to rule out cardiovascular risk.

"It represents the first cardiovascular safety trial of an anti-diabetic drug in patients with acute coronary syndromes. Hence, for those who are likely candidates for the drug in clinical practice with elevated CV risk,

including those with a recent acute coronary syndrome, it is reassuring that alogliptin does not increase cardiovascular morbidity or mortality," noted Dr. White.

"However, EXAMINE does not rule out longer-term benefits or risks of alogliptin with respect to cardiovascular end points as the median duration of the trial was approximately 18 months," he added.

The trial recruited 5,380 patients from 898 centers in 49 countries and randomized them to receive alogliptin or placebo, administered in a double-blind fashion along with standard-of-care treatment for type 2 diabetes mellitus and cardiovascular risk factors.

Due to its renal clearance, alogliptin dosing was modified according to kidney function, with 71.4% of patients receiving 25 mg, 25.7% receiving 12.5 mg, and 2.9% receiving 6.25 mg daily.

After a median follow-up of 18 months, and up to 40 months, the primary endpoint, which was a composite of cardiovascular death, myocardial infarction, and stroke had occurred at a similar rate in alogliptin and placebo-treated patients (11.3% vs 11.8% respectively; P