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Assessing the safety of sitagliptin in elderly participants in the Trial Evaluating Cardiovascular Outcomes with Sitagliptin (TECOS)

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Aims: TECOS was a randomised, double-blind, placebo-controlled trial assessing the impact of sitagliptin added to usual care on cardiovascular (CV) outcomes. We examined sitagliptin's safety profile in elderly (age≥75 years) TECOS patients.

Methods: Safety assessments of sitagliptin vs placebo were performed for key CV endpoints and pre specified safety endpoints in the intention-to-treat population. Exposure-adjusted event rates for CV endpoints with 95% confidence interval (CI) for the difference between rates (sitagliptin minus placebo) were calculated. Treatment-emergent adverse events (AEs) were assessed in the all-patients-as-treated population.

Results: There were 2,004 elderly patients (68% male, mean age78.3 years, mean diabetes duration 14.7 years) followed for a mean of 2.9 years (SD 1.0). The composite CV outcome rate (CV death, myocardial infarction or stroke) was higher in the elderly than the non-elderly population (6.0 vs 3.2 per 100 patient-years, difference 2.8, 95% CI 2.1–3.5), but there were no differences between treatment groups. Rates of heart failure requiring hospitalisation were higher in the elderly cohort (1.7 vs 1.0 per 100patient-years, difference 0.7, 95% CI 0.4–1.1) but did not differ between treatment groups. In elderly patients, rates of malignancies (6.2% in both groups), bone fractures (4.5% sitagliptin vs3.9% placebo) and hypoglycaemia (3.0% in both groups) were similar between treatment groups. Pancreatitis events were uncommon (sitagliptin 4, placebo 2). Incidences of treatment-emergent AEs and of diabetes-related complications were similar.

Conclusions: Sitagliptin was generally safe and well tolerated in elderly TECOS patients