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FIDELITY Analyses: Finerenone and Cardiorenal Outcomes by History of Cardiovascular Disease in Patients With Type 2 Diabetes

Dr. Filippatos:
Hello, my name is Gerasimos Filippatos. I'm from the National and Kapodistrian University of Athens and Attikon University Hospital. This presentation is on Fidelity Analyses, Finerenone, and Cardiorenal Outcomes by history of Atherosclerotic Cardiovascular Disease, in patients with Type 2 Diabetes and Chronic Kidney Disease.

Fidelity was a prespecified individual patient data-pooled analysis of the phase three FIDELIO-DKD and FIGARO-DKD trials that are part of the Finerenone clinical program. Finerenone is a novel selective nonsteroidal mineral corticoid receptor agonist and block Marvel activation, which is thought to contribute to kidney and cardiovascular damage. Inclusion criteria are shown in the gray box included estimate to glomerular filtration rate and urinary albumin to creatinine ratio or UACR Mapped on the KDIGO heat map. The key outcomes included a cardiovascular composite of time to cardiovascular death, non-fatal myocardial infection, non-fatal stroke, or hospitalization for Heart Failure, as well as a more equal to 57% eGFR kidney composite of time to kidney failure. Sustain more equal 57% decrease in eGFR from Baseline or kidney related death.

Finerenone was shown in fidelity to reduce the risk of clinically important cardiovascular and kidney outcomes versus placebo across the spectrum of chronic kidney disease in patients with type 2 diabetes. In this prespecified substudy of fidelity, the efficacy of Finerenone on cardiovascular and kidney outcomes was analyzed in primary-secondary prevention population. According to the history of Atherosclerotic Cardiovascular Disease. At Baseline patients with a history of Cardiovascular Disease had lowering eGFR and UACR than those without. Blood pressure and HBA1C did not defer by Cardiovascular Disease status. In the overall population, patients with a history of Cardiovascular Disease had a higher incidence of the composite cardiovascular outcome, cardiovascular death, or Heart Failure hospitalization and all cause mortality compared with patients without the history of Atherosclerotic Cardiovascular Disease. In contrast, the incidence of the composite kidney outcome did not defer between patients with or without the history of Atherosclerotic Cardiovascular Disease.

As noted previously the exploratory composite cardiovascular outcome was defined as time to cardiovascular death, non-fatal myocardial infection, non-fatal stroke or Heart Failure hospitalization. Finerenone consistently lower the risk of the composite cardiovascular outcome compared with placebo in patients with or without Atherosclerotic Cardiovascular Disease.

The table solves the composite cardiovascular outcome, cardiovascular death, or hospitalization for Heart Failure, composite kidney outcome, and all cause mortality by history of Atherosclerotic Cardiovascular Disease. In the overall fidelity population, Finerenone significantly reduce the risk of the primary composite cardiovascular outcome and composite kidney outcome compared with placebo. The risk of all cause mortality was numerically lower with Finerenone that with placebo but this difference was not significant. The effect of Finerenone on composite cardiovascular outcome, cardiovascular death or hospitalization for Heart Failure, composite kidney outcome and all cause mortality were consistent irrespective of history of cardiovascular status.

The safety profile of Finerenone did not defer between patients with and without Atherosclerotic Cardiovascular Disease. And Finerenone was generally well tolerated in both groups. There was a six to 8% absolute increase in treatment associated in hyperkalemia with Finerenone vascular placebo and approximately 1 in 100 patients required hospitalization for hyperkalemia. However,

rates of treatment discontinuation due to serious hyperkalemia were low. The risk of hyperkalemia did not appear to be modified by cardiovascular history.

In summary, patients with a history of Atherosclerotic Vascular Disease have a high risk of adverse cardiovascular outcomes. Finerenone reduce the risk of cardiovascular kidney outcomes consistently compared with placebo irrespective of history of Cardiovascular Disease status and was generally well-tolerated in both patient subgroups. These results indicate that Finerenone may be used for both primary and secondary cardiovascular disease prevention and for protection from worsening and kidney disease, in patients with type two diabetes at a broad spectrum of Chronic Kidney Disease. Thank you very much for your attention.