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Safety Outcomes Of Finerenone In Asian Patients With Type 2 Diabetes And Chronic Kidney Disease: A FIDELITY Analysis

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Objectives : Finerenone reduced the risk of cardiovascular and kidney events and showed a manageable safety profile in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) in FIDELITY, a prespecified pooled analysis of the phase III FIDELIO-DKD and FIGARO-DKD trials. This FIDELITY post-hoc subanalysis explored the safety of finerenone in Asian patients.
Methods : Patients with CKD (albuminuria and estimated glomerular filtration rate [eGFR] ≥25–90 ml/min/1.73 m^2) and T2D, and on optimised renin–angiotensin system blockade were randomised 1:1 to finerenone or placebo in FIDELIO-DKD and FIGARO-DKD. For this subgroup analysis, safety outcomes reported as treatment-emergent adverse events (including laboratory evaluations for hyperkalaemia) were assessed in the Asian subgroup and compared with the overall FIDELITY population.
Results : Of 12,999 patients with safety data, 22.2% self-identified as Asian. Safety outcomes were generally similar between treatment arms and comparable between the Asian subgroup and the overall population. As observed in the overall population, the incidence of treatment-emergent hyperkalaemia was higher with finerenone versus placebo. Incidence of investigator-reported hyperkalaemia was higher in Asian patients for both finerenone and placebo (20.2% vs 12.7%, respectively) compared with the overall population (14.0% vs 6.9%, respectively), but laboratory measurement of serum potassium values with finerenone and placebo were comparable between the Asian subgroup (>5.5 mmol/l: 15.7% vs 7.5%, respectively and >6.0 mmol/l: 4.5% vs 1.5%, respectively) and the overall population (>5.5 mmol/l: 16.8% vs 7.4%, respectively and >6.0 mmol/l: 3.3% vs 1.2%, respectively). Incidence of hyperkalaemia that led to treatment discontinuation and hospitalisation with finerenone and placebo were low in both populations. Incidence of acute kidney injury was similar between treatment arms and between both populations (Table 1).

Conclusions : In FIDELITY, finerenone demonstrated a well-balanced safety profile, with a manageable risk of hyperkalaemia in Asian patients.

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	Asian subgroup (N=2890)		Overall FIDELITY population (N=12,999)	
	Finerenone (n=1433)	Placebo (n=1457)	Finerenone (n=6510)	Placebo (n=6489)
Any AE	1335 (93.2)	1370 (94.0)	5602 (86.1)	5607 (86.4)
Any TE hyperkalaemia, n (%)	289 (20.2)	185 (12.7)	912 (14.0)	448 (6.9)
Leading to hospitalisation	15 (1.0)	1 (<0.1)	61 (0.9)	10 (0.2)
Leading to permanent discontinuation of study drug	21 (1.5)	9 (0.6)	110 (1.7)	38 (0.6)
AKI, n (%)	30 (2.1)	47 (3.2)	220 (3.4)	234 (3.6)
Leading to hospitalisation	14 (1.0)	18 (1.2)	85 (1.3)	86 (1.3)
Leading to permanent discontinuation of study drug	0 (0)	3 (0.2)	14 (0.2)	10 (0.2)
Serum potassium value, numerator/denominator (%)				
>5.5 mmol/l	223/1422 (15.7)	108/1443 (7.5)	1075/6402 (16.8)	470/6370 (7.4)
>6.0 mmol/l	64/1425 (4.5)	22/1448 (1.5)	211/6439 (3.3)	80/6413 (1.2)

All interruptions are excluded from the person-time at risk, i.e. for patients with an interruption, events in the period from interruption start +3 days until end of interruption are not considered.
AE, adverse event; AKI, acute kidney injury; eGFR, estimated glomerular filtration rate; TE, treatment emergent.