The effect of dapagliflozin on albuminuria in the DECLARE-TIMI 58 trial

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Running title: Albuminuria in the DECLARE-TIMI 58

Supplementary materials

Table S1: Distribution of categorical UACR at baseline and 6 months' time points in dapagliflozin vs. placebo arm.

Visit	UACR categories	Dapa	gliflozin	Pla			
		N	%	N	%	P-value	
	≤15 mg/g	4381	54.0%	4346	54.0%		
Baseline	15-<30 mg/g	1240	15.3%	1244	15.4%	0.9899	
	≥30-≤300 mg/g	1942	23.9%	1915	23.8%		
	>300 mg/g	555	6.8%	549	6.8%		
6 months	≤15 mg/g	4508	55.7%	4168	51.8%		
	15-<30 mg/g	1317	16.3%	1246	15.5%	<0.0001	
	≥30-≤300 mg/g	1853	22.9%	2019	25.1%		
	>300 mg/g	412	5.1%	591	7.3%		

Legends: Participants distribution within the UACR categories at baseline and at 6 months, among those with readings at both time points. Comparison between treatment arms was performed using the χ^2 test. UACR – Urinary Albumin to Creatinine Ratio

Figure S1: One time change in categorical UACR from baseline to end of trial (EOT) in dapagliflozin vs. placebo arm. A. Improvement in UACR categories B. Deterioration in UACR categories

A. Improvement

	Dapagliflozin (N=8582)			Plac	ebo (N=8	3578)			
	n	N	n/N(%)	n	N	n/N(%)		Hazard ratio (95% CI)	Cox p-value
Reduction of UACR to <=300 in subjects with >300 at BL	402	594	67.7%	304	575	52.9%		1.55 (1.33, 1.80)	<0.0001
Reduction of UACR to <30 in subjects with 30–300 at BL	1208	2017	59.9%	1006	2013	50.0%		1.36 (1.25, 1.47)	<0.0001
Reduction of UACR to <=15 in subjects with >15-<30 at BL	952	1281	74.3%	855	1296	66.0%		1.26 (1.15, 1.39)	<0.0001
Stable UACR at <=15 in subjects with <=15 at BL	4253	4538	93.7%	4155	4529	91.7%	-	1.08 (1.04, 1.13)	0.0003
Reduction of UACR of at least 1–step improvement in subjects with >15 at BL	2562	3892	65.8%	2165	3884	55.7%	-	1.34 (1.27, 1.42)	<0.0001
Reduction of UACR 2–step Improvement in subjects with >=30 at BL	882	2611	33.8%	692	2588	26.7%		1.34 (1.21, 1.48)	<0.0001
	0.80 1.0 1.4 1.8 < favored Placebo favored Dapaglililozin>								

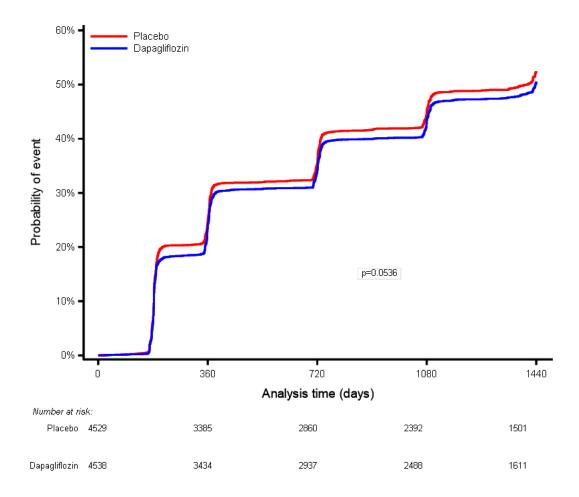
B. Deterioration

1	Dapagliflozin (N=8582)		Placebo (N=8578)						
	n	N	n/N(%)	n	N	n/N(%)		Hazard ratio (95% CI)	Cox p-value
Progression of UACR to >15 in subjects with <=15 at BL	2389	4538	52.6%	2453	4529	54.2%	-	0.95 (0.89, 1.00)	0.0570
Pogression of UACR to >=30 in subjects <30 at BL	1964	5819	33.8%	2234	5825	38.4%	-	0.84 (0.79, 0.89)	<0.0001
Progression of UACR to >300 in subjects with 30–300 at BL	414	2017	20.5%	597	2013	29.7%		0.65 (0.57, 0.73)	<0.0001
Progression of UACR at least 1-step deterioration in subjects with <=300 at BL	3558	7836	45.4%	3930	7838	50.1%	-	0.86 (0.82, 0.90)	<0.0001
Development of UACR 2–step deterioration in subjects with <30 at BL	1257	5819	21.6%	1461	5825	25.1%	-	0.84 (0.78, 0.90)	<0.0001
							0.55 0.75 1.0 favored Dapagliflozin	1.2 favored Placebo>	

Figure S2: Deterioration in categorical albuminuria status over time (Kaplan-Meier estimate):

- A- New onset of >15 mg/g in patients with ≤15 mg/g at baseline
- B- New onset of >=30 mg/g in patients with <30 mg/g at baseline
- C- New onset of >300 mg/g in patients with <=300 mg/g at baseline

A-



P=0.0536



