

MedDRA system organ class	n (KM event rate)		Hazard Ratio [95% CI]	p-value
	Dapagliflozin (N=8582)	Placebo (N=8578)		
Cardiac disorders	1034 (12.1%)	1119 (12.9%)	0.91 [0.84-1.00]	0.039
Infections and infestations	664 (7.7%)	763 (8.8%)	0.86 [0.78-0.96]	0.0048
Nervous system disorders	440 (5.0%)	457 (5.3%)	0.96 [0.84-1.09]	0.51
Neoplasms benign malignant and unspecified (incl cysts and polyps)	289 (3.3%)	308 (3.6%)	0.93 [0.79-1.09]	0.39
Injury poisoning and procedural complications	300 (3.5%)	288 (3.2%)	1.04 [0.88-1.22]	0.65
Gastrointestinal disorders	249 (2.8%)	253 (3.0%)	0.98 [0.82-1.17]	0.83
Metabolism and nutrition disorders	173 (2.0%)	235 (2.7%)	0.73 [0.60-0.89]	0.0018
Musculoskeletal and connective tissue disorders	191 (2.2%)	233 (2.7%)	0.81 [0.67-0.99]	0.035
Vascular disorders	250 (3.0%)	230 (2.6%)	1.08 [0.91-1.30]	0.38
Renal and urinary disorders	119 (1.4%)	192 (2.2%)	0.61 [0.49-0.77]	<0.0001
Respiratory thoracic and mediastinal disorders	158 (1.9%)	192 (2.2%)	0.82 [0.66-1.01]	0.062
General disorders and administration site conditions	174 (2.0%)	187 (2.1%)	0.92 [0.75-1.14]	0.45
Other	379 (4.4%)	449 (5.1%)	0.84 [0.73-0.96]	0.011
Any-cause excluding cardiac-, renal and urinary-, and metabolism and nutrition- disorders	2086 (24.1%)	2263 (25.9%)	0.90 [0.85-0.96]	0.0009

