Supplement to: Natriuretic effect of 2 weeks of dapagliflozin treatment in patients with type 2 diabetes and preserved kidney function during standardized sodium intake: Results of the DAPASALT trial

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Content:

Supplementary Table 1: Changes in primary and secondary outcomes in the intention to treat population (N=15)

		Change from baseline		**Change from End of Treatment**
	Baseline Mean (SD)	Start of Treatment (Day 2-4) Mean change (95% CI)	End of Treatment (Day 12-14) Mean change (95% CI)	Follow-up (Day 15-17) Mean change (95% CI)
24-hour sodium excretion (mmol/24 hour)	147.37 (32.17)	–5.21 (–19.54, 9.12)	3.69 (–24.82, 32.20)	–16.72 (–34.11, 0.66)
24-hour glucose excretion (mmol/24 hour)	1.80 (2.16)	344.85 (272.79, 416.91)	311.30 (224.53, 398.06)	–203.07 (–235.98, –170.16)
24-hour volume excretion (mL/24 hour)	2238.08 (594.82)	57.23 (–206.00, 320.47)	108.68 (–170.27, 387.63)	–214.33 (–437.15, 8.49)
24-hour systolic blood pressure (mmHg)	127.00 (10.28)	–5.27 (–8.55, –1.99)	–7.10 (–10.04, –4.16)	0.73 (–1.99, 3.45)
Body weight (kg)	97.75 (15.77)	–0.73 (–1.12, –0.35)	–1.68 (–2.37, –1.00)	0.45 (0.02, 0.89)
Plasma volume (L)	3.68 (0.78)	0.03 (–0.73, 0.79)	–0.43 (–1.08, 0.21)	0.48 (0.10, 0.85)
Extracellular volume (L)	20.93 (4.32)	–0.67 (–1.19, –0.15)	–0.03 (–0.46, 0.40)	0.17 (–0.14, 0.48)
Intracellular volume (L)	26.41 (5.54)	–0.27 (–0.90, 0.35)	0.14 (–0.52, 0.79)	–0.33 (–0.66, –0.00)

Supplementary Table 2: 24-hour sodium, glucose, urine excretion at each collection day

Period	**Run-in**			**Dapagliflozin 10 mg/day treatment**							**Wash-out**		
Day	-3	-2	-1	1	2	3	4	12	13	14	15	16	17
Sodium	161	153	129	156	156	136	136	153	166	135	137	138	143
(mmol/24 hour)	(42)	(33)	(36)	(45)	(37)	(42)	(31)	(54)	(79)	(79)	(50)	(38)	(41)
Glucose	2	2	3	258	369	338	351	325	321	327	202	94	54
(mmol/24 hour)	(2)	(2)	(4)	(57)	(134)	(143)	(141)	(148)	(144)	(172)	(135)	(107)	(79)
Volume	2437	2269	1988	2148	2411	2401	2201	2474	2487	2136	2341	2137	2125
(mL/24-hour)	(537)	(666)	(699)	(726)	(710)	(874)	(619)	(857)	(868)	(690)	(568)	(696)	(631)

Data are provided as mean (SD)

Supplementary Table 3: Adverse events

Variable	Dapagliflozin (N=17)*
Any Adverse Events	6 (35.3)
Any Serious Adverse Events	0 (0.0)
Any Adverse Event leading to drug discontinuation	0 (0.0)
Adverse Events related to dapagliflozin[#]	4 (23.5)
Adverse Events of interest[†]	
Hypoglycemia	0 (0.0)
Genital infection	1 (5.9)

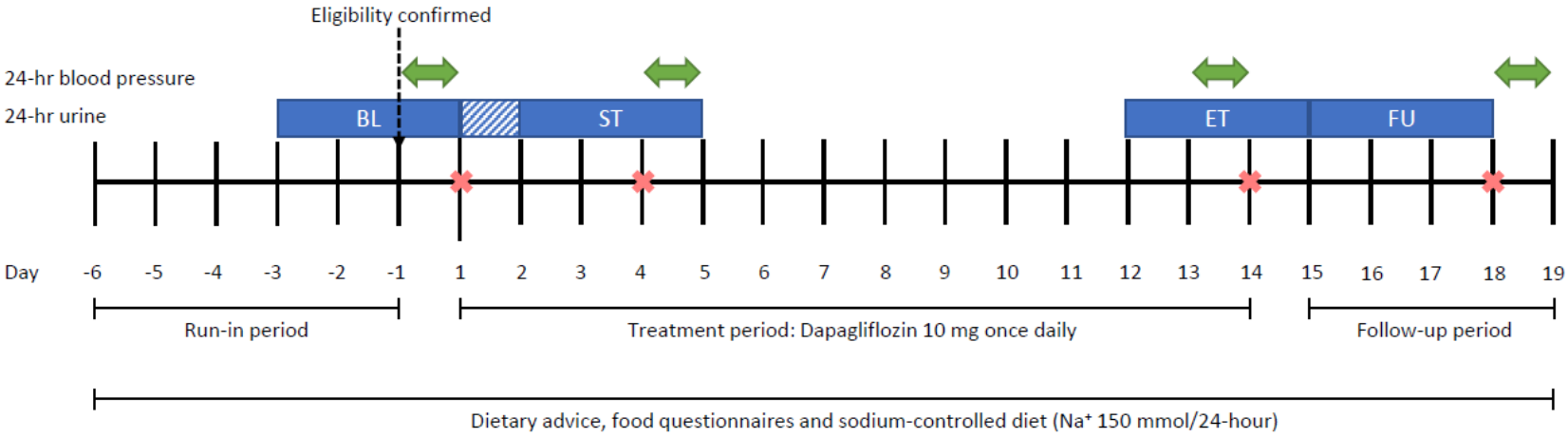
*Safety population (N) comprised 17 patients who took at least 1 dapagliflozin tablet.

[#]In the opinion of the Investigator.

Data are expressed as number of patients in each category, n (%).Patients with multiple events in the same category are counted only once in that category.

[†]Based on MedDRA (Medical Dictionary for Regulatory Activities) preferred term.

Supplementary Figure 1: Study design



✖ = Blood and urine samples collected, bioimpedance spectroscopy measurements and plasma volume measurements were performed at Day 1, Day 4, Day 14 and Day 18.

⟷ = 24-hour blood pressure monitoring was initiated at Day -1, Day 4, Day 13 and Day 18.

■ = 24-hour urine assessment was performed at BL (Days -3 to -1), ST (Days 2 to 4), ET (Days 12 to 14) and FU (Days 15 to 17).

▨ = 24-hour urine collection (not included in assessment).

BL, baseline; ST, start of treatment; ET, end of treatment; FU, follow-up