

Supplement to Early response in albuminuria and long-term kidney protection during treatment with an endothelin receptor antagonist– a pre-specified analysis from the SONAR trial

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Supplemental Figure 1: Effect of atrasentan compared to placebo on rate of eGFR decline during the double blind treatment period according to UACR response during the response enrichment period

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Supplement table 1: Baseline characteristics according pre-defined UACR response strata

	UACR ≥ 60%		UACR 45 – 60%		UACR 30-45%		UACR 15- 30%		UACR 0 – 15%		UACR<0%	
	Atrasentan	Placebo	Atrasentan	Placebo	Atrasentan	Placebo	Atrasentan	Placebo	Atrasentan	Placebo	Atrasentan	Placebo
N patients (%)	297	294	484	484	544	545	241	238	142	144	126	129
Age, years*	65.5 (8.5)	65.6 (8.6)	64.9 (8.2)	64.2 (8.6)	64.5 (9.0)	64.7 (8.7)	64.0 (9.6)	65.0 (8.7)	63.3 (9.0)	62.8 (9.1)	63.8 (8.3)	62.0 (8.9)
Sex												
Male	214 (72.1)	206 (70.1)	365 (75.4)	351 (72.5)	415 (76.3)	414 (76.0)	181 (75.1)	175 (73.5)	107 (75.4)	112 (77.7)	94 (74.6)	88 (68.2)
Female	83 (27.9)	88 (29.9)	119 (24.6)	133 (27.5)	129 (23.7)	131 (24.0)	60 (24.9)	63 (26.5)	35 (24.6)	32 (22.2)	32 (25.4)	41 (31.8)
Body Weight, (kg)	83.8 (20)	84.8 (18)	83.8 (21)	84.7 (20)	85.8 (19)	84.5 (18)	88.5 (22)	86.2 (18)	86.0 (19)	85.8 (19)	87.3 (20)	87.1 (22)
Systolic BP, mmHg	136.9 (15)	137.8 (15)	136.8 (14)	136.0 (15)	135.9 (16)	135.5 (15)	135.8 (15)	135.2 (16)	135.7 (16)	135.3 (17)	138.4 (15)	136.1 (17)
Diastolic BP, mmhg	75.2 (10)	74.9 (10)	74.7 (10)	74.9 (10)	75.2 (10)	74.8 (10)	74.3 (11)	74.2 (10)	75.2 (10)	75.0 (10)	76.2 (10)	75.4 (9)
Hba1c, (mmol/mol)	7.5 (1.4)	7.7 (1.6)	7.6 (1.4)	7.5 (1.3)	7.6 (1.4)	7.6 (1.5)	7.5 (1.3)	7.7 (1.6)	7.6 (1.5)	7.8 (1.7)	7.7 (1.6)	7.5 (1.5)
S. creatinine, (µmol/L)*	150.3 (40)	152.8 (44)	147.8 (43)	145.5 (41)	151.0 (43)	152.2 (42)	159.7 (49)	156.3 (47)	149.9 (44)	159.9 (45)	140.7 (44)	141.6 (40)
eGFR, ml/min/1.73m ²	46.1 (14)	45.1 (15)	44.0 (14)	44.3 (14)	42.8 (13)	42.4 (13)	40.9 (15)	41.5 (14)	43.9 (15)	41.0 (13)	42.8 (12)	41.8 (12)
Serum Albumin, g/L*	40.0 (3.4)	39.7 (3.4)	39.5 (3.6)	39.1 (3.3)	38.9 (3.5)	39.2 (3.5)	38.7 (3.7)	38.6 (3.9)	38.4 (3.8)	38.3 (3.9)	39.0 (3.7)	38.4 (3.6)
Hemoglobin, g/L	129.9 (17)	127.3 (17)	129.8 (17)	128.3 (17)	129.9 (17)	130.0 (17)	130.5 (18)	130.3 (17)	129.8 (18)	126.5 (17)	128.8 (19)	126.1 (17)
BNP, pg/ml	53.0 [27, 91]	58.0 [29, 101]	49.5 [27, 89]	48.0 [25, 87]	47.0 [25, 82]	45.0 [25, 82]	48.0 [26, 84]	42.5 [23, 78]	49.0 [26, 82]	41.0 [25, 87]	45.5 [27, 73]	56.0 [27, 95]
UACR, mg/g*	662 [399, 1180]	652 [373, 1188]	820 [469, 1415]	781 [442, 1435]	877 [486,1671]	887 [512, 1582]	955 [529, 1858]	926 [447, 1879]	1161 [520, 2284]	1048 [554, 2142]	808.0 [436, 1475]	756.5 [395, 1467]
<i>Medication use‡</i>												
Diuretics	247 (83.2)	253 (86.1)	408 (84.3)	409 (84.5)	453 (83.3)	450 (82.6)	204 (84.6)	192 (80.7)	117 (82.4)	117 (81.3)	106 (84.1)	109 (84.5)
Beta-blockers	144 (48.5)	127 (43.2)	216 (44.6)	203 (41.9)	206 (37.9)	222 (40.7)	98 (40.7)	91 (38.2)	53 (37.3)	68 (47.2)	57 (45.2)	46 (35.7)
Lipid lowering drugs	225 (75.8)	228 (77.6)	381 (78.7)	380 (78.5)	427 (78.5)	452 (82.9)	198 (82.2)	201 (84.5)	107 (75.4)	114 (79.2)	99 (78.6)	101 (78.3)

‡All patients had to be on a maximum tolerated dose of an ACE-inhibitor or ARB. Abbreviations: BP, blood pressure; BNP, B-type natriuretic peptide; eGFR, estimated glomerular filtration rate; UACR, urine protein: urine creatinine ratio. Numeric variables are presented as mean (SD) or median [25th to 75th Percentile] where appropriate. Categorical variables are presented as counts (%). *p-value across UACR response strata <0.001; ‡p-value across UACR response strata 0.0284

Supplement Table 2: Baseline characteristics of participants with available eGFR data prior to enrollment in the SONAR trial

Characteristics	Participants with pre-intervention eGFR slope	SONAR (overall)
Number of patients	532	3668
Age, years	64.7 (8.5)	64.5 (8.8)
Gender		
Male	419 (78.8%)	2722 (74.2%)
Female	113 (21.2%)	946 (25.8%)
Race, n (%)		
White	317 (59.6%)	2110 (57.5%)
Black	10 (1.9%)	224 (6.1%)
Asian	191 (35.9%)	1198 (32.7%)
Other	14 (2.6%)	136 (3.7%)
Blood pressure		
Systolic, mm Hg	136.5 (14.9)	136.2 (15.2)
Diastolic, mm Hg	74.4 (10.1)	74.9 (9.9)
Serum creatinine, $\mu\text{mol/L}$	148.9 (41.6)	149.7 (43.2)
eGFR, mL/min/1.73 m ²	43.7 (13.8)	43.3 (13.8)
Hemoglobin, g/L	131.0 (16.5)	129.3 (17.1)
HbA1c, %	7.5 (1.4)	7.6 (1.5)
Serum Albumin, g/L	39.7 (3.5)	39.1 (3.6)
UACR, mg/g	820 [475 - 1553]	829 [457 - 1556]
Medications		
Diuretics, n (%)	465 (87.4)	3055 (83.6)
Beta-blockers, n (%)	273 (51.3)	1531 (41.7)
Lipid-lowering, n (%)	460 (86.5)	2913 (79.4)

Data are n (%), mean (SD), or median [25th to 75th Percentile].

eGFR = estimated glomerular filtration rate; HbA1c = glycated hemoglobin; UACR = urinary albumin-to-creatinine ratio.

Supplement table 3: Changes in risk markers of cardiovascular and kidney disease progression in predefined UACR response strata during the response enrichment period. Shown are mean (SD) except for B-type Natriuretic Peptide which is presented as percentage geometric mean change (95%CI).

	UACR ≥ 60%	UACR 45 – 60%	UACR 30-45%	UACR 15- 30%	UACR 0 – 15%	UACR<0%
Blood pressure						
Systolic	-6.6 (15)	-6.5 (14)	-5.5 (15)	-2.9 (15)	-1.7 (16)	-1.0 (16)
Diastolic	-5.2 (9)	-5.3 (9)	-4.8 (9)	-3.0 (9)	-2.7 (10)	-2.4 (9)
eGFR	-2.3 (7.4)	-1.7 (6.3)	-0.8 (6.2)	-0.3 (5.9)	-0.1 (5.4)	1.4 (7.4)
Body weight	0.4 (1.5)	0.5 (1.7)	0.6 (1.5)	0.6 (1.5)	0.7 (1.5)	0.6 (1.8)
B-type Natriuretic Peptide	1.1 (-4.3, 6.7)	6.0 (1.7, 10.5)	9.0 (5.0, 13.1)	8.8 (2.9, 15.0)	9.2 (1.9, 16.9)	11.9 (2.9, 21.7)

Supplement table 4: Effects of atrasentan compared to placebo on systolic blood pressure during double blind treatment in UACR response strata.

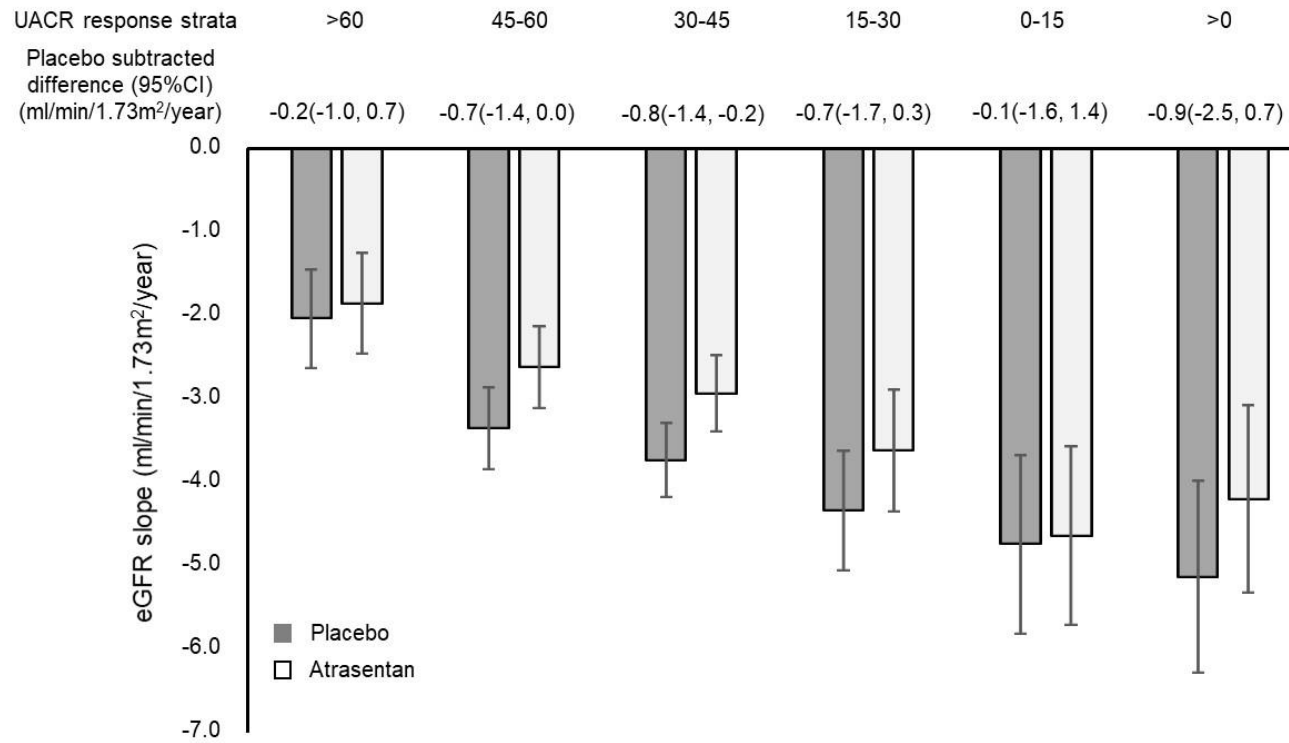
UACR response stratum	Least square mean systolic blood pressure during double blind treatment (95%CI)		Difference Atrasentan vs Placebo
	Atrasentan (N=1834)	Placebo (N=1834)	
≥ 60% reduction	135.6 (134.1, 137.0)	139.0, (137.6, 140.4)	-3.37 (-5.39, -1.34)
45 to 60% reduction	137.4 (136.3, 138.5)	138.6 (137.5, 139.7)	-1.15 (-2.69, 0.40)
30 to 45% reduction	137.3 (136.2, 138.4)	138.8 (137.8, 139.9)	-1.54 (-3.02, -0.05)
15 to 30% reduction	138.5 (137.0, 140.0)	138.4 (136.9, 139.9)	0.10 (-2.04, 2.25)
0 to 15% reduction	138.7 (136.7, 140.7)	139.8 (137.8, 142.8)	-1.11 (-3.96, 1.73)
≥0% increase	139.0 (136.7, 141.3)	138.2 (136.0, 140.5)	0.77 (-2.44, 3.98)

Supplement table 5: Number of patients (percentages) in whom thiazide, loop, and potassium sparing diuretic treatment was escalated during enrichment in each UACR response stratum.

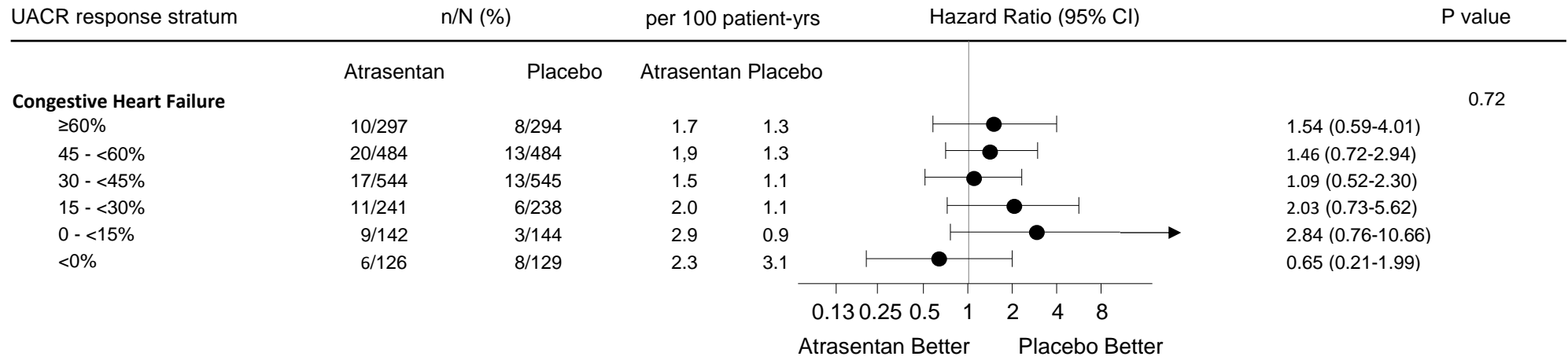
UACR response stratum	Thiazide-diuretics	Loop-diuretics	Potassium-sparing diuretics
≥ 60% reduction	36 (6.1)	130 (22.0)	0 (0.0)
45 to 60% reduction	64 (6.6)	177 (18.3)	2 (0.2)
30 to 45% reduction	58 (5.3)	157 (14.4)	2 (0.2)
15 to 30% reduction	22 (4.6)	89 (18.6)	0 (0.0)
0 to 15% reduction	13 (4.6)	47 (16.4)	0 (0.0)
≥0% increase	15 (5.9)	31 (12.2)	0 (0.0)

Some patients started both thiazide and loop-diuretics and therefore the total numbers exceed those in table 3 for a couple of subgroups. Thiazide diuretics initiated during enrichment include hydrochlorothiazide, chlorthalidone, indapamide, metolazone; Loop diuretics include furosemide and torazemide; Potassium sparing diuretic is spironolactone

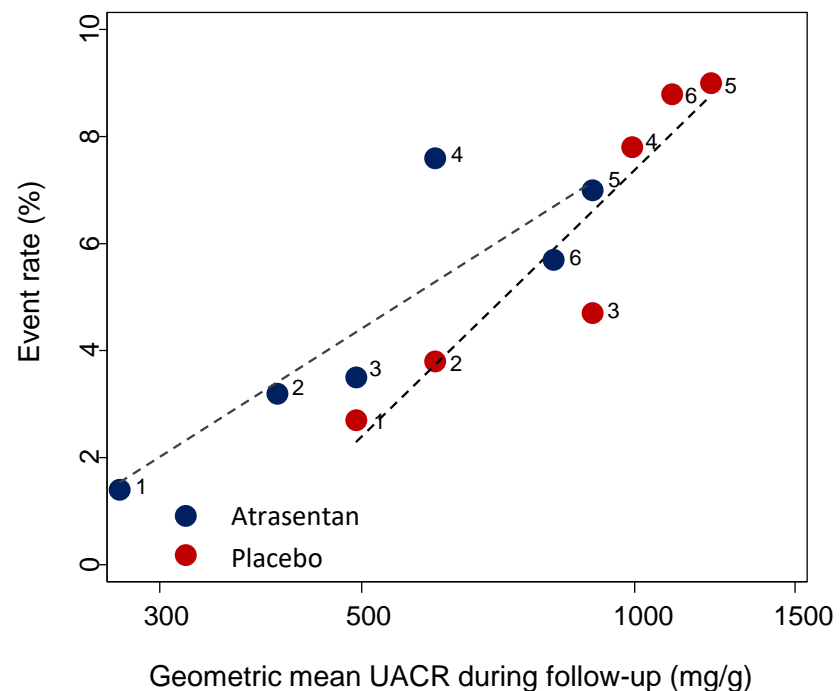
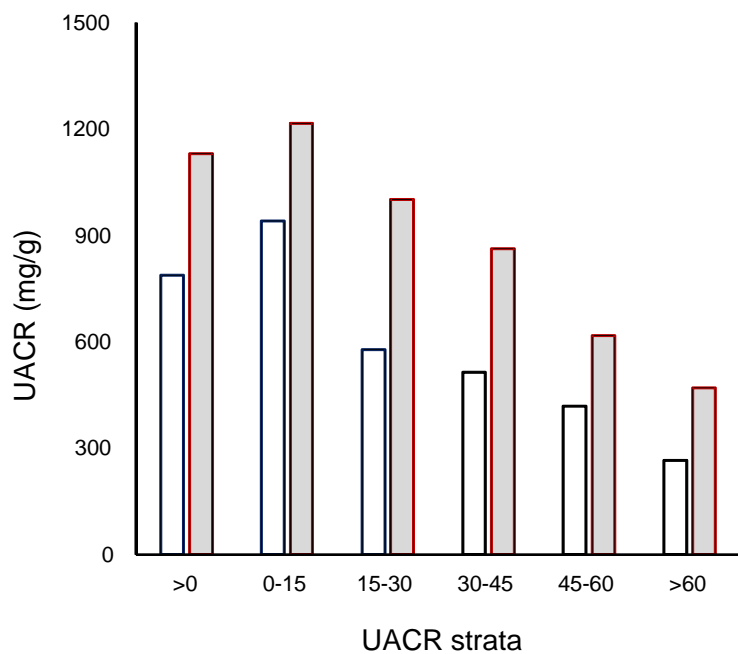
Supplement figure 1: Effect of atrasentan compared to placebo on rate of eGFR decline during the double blind treatment period according to UACR response during the response enrichment period



Supplement figure 2: Effect of atrasentan compared to placebo on hospitalizations for heart failure during the double blind treatment period according to UACR response during the response enrichment period



Supplement Figure 3: Association between the geometric mean UACR level achieved during double blind treatment and event rate for the primary kidney outcome according to the UACR response recorded during the response enrichment period. The association is displayed for participants who were randomized to continue atrasentan (blue dots; $R^2=0.76$; $p=0.024$) and randomized to transition to placebo (red dots; $R^2=0.88$; $p=0.006$). Numbers in the figure indicate the UACR response strata: 1, $\leq -60\%$; 2, -60% to $\leq -45\%$; 3, -45% to $\leq -30\%$; 4, -30% to $\leq -15\%$; 5, -15% to $\leq 0\%$; 6, $>0\%$



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United States of America	VA Medical Center, White River Junction	Brooks Robey
United States of America	JM Research, Houston	Jose Flores
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