Errata to the Sponsor's Briefing Document ReCor Medical Circulatory System Devices Panel August 22, 2023

Page 77, Figure 33	X-Axis label corrected to mean difference
	Δ SBP at 2 months corrected to show means
	N for uRDN Home SBP < 151 corrected to be N=67
	N for Sham 24-hr AHR ≥ 72 corrected to be N=33

Figure 33: RADIANCE II: Subgroup Analysis of Primary Efficacy – Mean Changes in Daytime Ambulatory SBP by Patient Characteristics (ITT Population)

		∆ SBP at 2 Months (n)			
		uRDN	Sham	Favors uRDN	Interaction p-value
Sex	Male	-8.4 (99)	-2.2 (56)		0.912
	Female	-6.7 (46)	-0.6 (17)	• • ••••	0.912
Race	Black	-10.7 (20)	-2.2 (14)	·	0.054
	Not Black	-7.4 (125)	-1.8 (59)	→→	0.654
Age	< 56	-8.1 (69)	-1.0 (35)	⊢	0.050
	≥ 56	-7.7 (76)	-2.7 (38)		0.253
Location	US	-7.6 (97)	-3.3 (45)	⊢	0.450
	OUS	-8.5 (48)	0.5 (28)	→	0.150
Abdominal Obesity	Yes	-7.1 (87)	-1.2 (45)	→	0.593
	No	-9.0 (58)	-2.9 (28)	⊢	0.583
Daytime ASBP	< 149	-6.6 (72)	-0.4 (33)	⊢_	0.400
	≥ 149	-9.2 (73)	-3.1 (40)	⊢	0.460
Office SBP	< 156	-9.5 (69)	-1.9 (40)	⊢	0.700
	≥ 156	-6.4 (76)	-1.8 (33)	⊢	0.709
Home SBP	< 151	-8.4 (67)	-1.7 (41)	⊢	0.574
	≥ 151	-7.6 (76)	-2.1 (31)	⊢	0.574
24-hr AHR	< 72	-6.0 (68)	-2.0 (40)	⊢	0.000
	≥ 72	-9.5 (77)	-1.7 (33)	⊢ →	0.232

Change from Baseline in Daytime Ambulatory SBP (mmHg) Mean Difference (uRDN – Sham)

AHR=ambulatory heart rate; OUS=outside United States; SBP=systolic blood pressure; uRDN=ultrasound renal denervation, US=United States

N for uRDN abdominal obesity corrected to N=41

Figure 38: SOLO: Subgroup Analysis of Primary Efficacy – Mean Changes in Daytime Ambulatory SBP by Patient Characteristics (ITT Population)

		Δ SBP at 2 Months (n)			
		uRDN	Sham	Favors uRDN	Interactior p-value
Sex	Male	-7.9 (46)	-1.7 (39)		0.659
	Female	-9.4 (28)	-2.8 (33)		0.059
Dees	Black	-7.0 (12)	-2.2 (13)		0.042
Race	Not Black	-8.7 (62)	-2.2 (59)		0.813
A	< 55	-9.8 (33)	-1.7 (35)		0.000
Age	≥ 55	-7.3 (41)	-2.6 (37)	⊢	0.328
	US	-11.0 (35)	-2.6 (34)		0.400
Location	OUS	-6.2 (39)	-1.8 (38)		0.180
Abdominal Obesity	Yes	-10.1 (41)	0.0 (44)		0.015
	No	-6.7 (32)	-5.6 (28)		0.015
Daytime ASBP	< 150	-7.2 (39)	-1.4 (35)		0.390
	≥ 150	-9.9 (35)	-2.9 (37)		0.390
Office SBP	< 154	-9.9 (36)	-1.9 (34)	⊢ ◆→	0.240
	≥ 154	-7.1 (38)	-2.4 (38)		0.340

Change from Baseline in Daytime Ambulatory SBP (mmHg) Mean Difference (uRDN – Sham)

AHR=ambulatory heart rate; OUS=outside United States; SBP=systolic blood pressure; uRDN=ultrasound renal denervation, US=United States

Page 95, Figure 42 Female \triangle SBP at 2 months in sham corrected to -1.3

Figure 42: TRIO: Subgroup Analysis of Primary Efficacy – Mean Changes in Daytime Ambulatory SBP by Patient Characteristics (ITT Population)

		∆ SBP at 2 Months (n)			
		uRDN	Sham	Favors uRDN	Interaction p-value
Sex	Male	-7.4 (56)	-3.3 (53)		0.6294
Sex	Female	-15.2 (13)	-1.3 (14)		0.0294
Deee	Black	-9.8 (14)	-5.0 (13)		0 7040
Race	Not Black	-7.4 (55)	-3.0 (54)		0.7248
A	< Median	-8.0 (38)	-5.0 (30)		0.4005
Age	≥ Median	-8.0 (31)	-1.7 (37)		0.4605
Lasatian	US	-10.5 (28)	-3.0 (25)		0.0040
Location	OUS	-5.9 (41)	-3.1 (42)		0.0846
Abdominal	Yes	-8.7 (54)	-3.6 (55)		0.4445
Obesity	No	-10.0 (12)	-0.3 (12)		0.4115
Daytime ASBP	< Median	-7.2 (36)	-3.6 (32)		0.0054
	≥ Median	-12.7 (33)	-1.7 (35)		0.2251
Office SBP	< Median	-7.3 (33)	-2.5 (32)		0.0700
	≥ Median	-10.1 (36)	-3.9 (35)		0.9702

Change from Baseline in Daytime Ambulatory SBP (mmHg) Median Difference (uRDN – Sham)

AHR=ambulatory heart rate; OUS=outside United States; SBP=systolic blood pressure; uRDN=ultrasound renal denervation, US=United States