

Table 15.12.2.1: Analysis of Response Rate in TSS at Week 24 and at Week 12
Double-Blind Phase
Intent-to-Treat Analysis Set

	MMB (N=215)	RUX (N=217)	Total (N=432)
All Strata Combined			
Total Symptom Score Status			
Missing TSS at baseline (excluded from rate calculation)	2 (0.9%)	3 (1.4%)	5 (1.2%)
TSS = 0 at baseline	3 (1.4%)	3 (1.4%)	6 (1.4%)
TSS > 0 at baseline	210 (97.7%)	211 (97.2%)	421 (97.5%)
Response Rate of Total Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	211	211	422
TSS = 0 at baseline and TSS >0 or missing at Week 24	1 (0.5%)	0	1 (0.2%)
Responder, n(%)			
95% Exact CI	60 (28.4%) 0.2245, 0.3503	89 (42.2%) 0.3543, 0.4915	149 (35.3%) 0.3075, 0.4008
Noninferior Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-0.08, 0.08)		
p-value	0.98		
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.00 (-0.07, 0.08)		
p-value	0.96		
Superior Proportion Difference - Stratified CMH Method (95% CI)	-0.14 (-0.23, -0.05)		
p-value	0.003		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.14 (-0.23, -0.05)		
p-value	0.003		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.14 (-0.23, -0.04)		
p-value	0.004		
Non-Responder, n(%)			
Last participation date < Day 162 in DB phase	151 (71.6%) 31 (14.7%)	122 (57.8%) 12 (5.7%)	273 (64.7%) 43 (10.2%)
Last participation date >= Day 162 and TSS at Week 24 not available	5 (2.4%)	9 (4.3%)	14 (3.3%)
>0% increase from baseline at Week 24	47 (22.3%)	32 (15.2%)	79 (18.7%)
<50% reduction from baseline week 24	114 (54.0%)	101 (47.9%)	215 (50.9%)

95% Exact CI is based on Clopper-Pearson method without stratification.

TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.

TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Source: Listing 16.3.2.1

Data Extracted: CRF data: 01JUL2019

Source: ...\\version5\prog\t-tss24.sas v9.4 Output file: t-tss24.out 09MAR2021:19:52

Table 15.12.2.1: Analysis of Response Rate in TSS at Week 24 and at Week 12
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	MMB (N=215)	RUX (N=217)	Total (N=432)
Response Rate of Total Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	212	213	425
TSS = 0 at baseline and TSS >0 or missing at Week 12	2 (0.9%)	2 (0.9%)	4 (0.9%)
Responder, n(%)	58 (27.4%)	74 (34.7%)	132 (31.1%)
95% Exact CI	0.2148, 0.3389	0.2837, 0.4155	0.2669, 0.3570
Noninferior Proportion Difference - Stratified CMH Method (95% CI)	0.04 (-0.03, 0.12)		
p-value	0.28		
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.04 (-0.03, 0.11)		
p-value	0.28		
Superior Proportion Difference - Stratified CMH Method (95% CI)	-0.07 (-0.16, 0.02)		
p-value	0.11		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.07 (-0.16, 0.01)		
p-value	0.100		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.07 (-0.17, 0.02)		
p-value	0.12		
Non-Responder, n(%)	154 (72.6%)	139 (65.3%)	293 (68.9%)
Last participation date < Day 78 in DB phase	16 (7.5%)	2 (0.9%)	18 (4.2%)
Last participation date >= Day 78 and TSS at Week 12 not available	5 (2.4%)	7 (3.3%)	12 (2.8%)
>0% increase from baseline at Week 12	50 (23.6%)	37 (17.4%)	87 (20.5%)
<50% reduction from baseline at week 12	131 (61.8%)	128 (60.1%)	259 (60.9%)

95% Exact CI is based on Clopper-Pearson method without stratification.

TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.

TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

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Intent-to-Treat Analysis Set

	MMB (N=215)	RUX (N=217)	Total (N=432)
Stratum 1			
Transfusion Dependence Yes and Platelet Count < 100X10E9/L	10	11	21
Total Symptom Score Status			
Missing TSS at baseline (excluded from rate calculation)	1 (10.0%)	0	1 (4.8%)
TSS = 0 at baseline	0	0	0
TSS > 0 at baseline	9 (90.0%)	11 (100.0%)	20 (95.2%)
Response Rate of Total Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	9	11	20
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	0	0
Responder, n(%)			
95% Exact CI	2 (22.2%)	3 (27.3%)	5 (25.0%)
95% Exact CI	0.0281, 0.6001	0.0602, 0.6097	0.0866, 0.4910
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.04 (-0.31, 0.39)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.05 (-0.46, 0.36)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.05 (-0.46, 0.38)		
Non-Responder, n(%)			
Last participation date < Day 162 in DB phase	7 (77.8%)	8 (72.7%)	15 (75.0%)
Last participation date >= Day 162 and TSS at Week 24 not available	1 (11.1%)	3 (27.3%)	4 (20.0%)
Last participation date >= Day 162 and TSS at Week 24 not available	0	1 (9.1%)	1 (5.0%)
>0% increase from baseline at Week 24	4 (44.4%)	1 (9.1%)	5 (25.0%)
<50% reduction from baseline week 24	6 (66.7%)	4 (36.4%)	10 (50.0%)

95% Exact CI is based on Clopper-Pearson method without stratification.

TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.

TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

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Response Rate of Total Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	9	11	20
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	0	0
Responder, n(%)	2 (22.2%)	4 (36.4%)	6 (30.0%)
95% Exact CI	0.0281, 0.6001	0.1093, 0.6921	0.1189, 0.5428
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	-0.02 (-0.38, 0.34)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.14 (-0.57, 0.28)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.14 (-0.54, 0.29)		
Non-Responder, n(%)	7 (77.8%)	7 (63.6%)	14 (70.0%)
Last participation date < Day 78 in DB phase	1 (11.1%)	0	1 (5.0%)
Last participation date >= Day 78 and TSS at Week 12 not available	0	1 (9.1%)	1 (5.0%)
>0% increase from baseline at Week 12	5 (55.6%)	2 (18.2%)	7 (35.0%)
<50% reduction from baseline at week 12	6 (66.7%)	6 (54.5%)	12 (60.0%)

95% Exact CI is based on Clopper-Pearson method without stratification.

TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.

TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

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Intent-to-Treat Analysis Set

	MMB (N=215)	RUX (N=217)	Total (N=432)
Stratum 2			
Transfusion Dependence Yes and Platelet Count $\geq 100 \times 10^9/L$ and $\leq 200 \times 10^9/L$	21	20	41
Total Symptom Score Status			
Missing TSS at baseline (excluded from rate calculation)	0	0	0
TSS = 0 at baseline	1 (4.8%)	0	1 (2.4%)
TSS > 0 at baseline	20 (95.2%)	20 (100.0%)	40 (97.6%)
Response Rate of Total Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	20	20	40
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	0	0
Responder, n(%)			
95% Exact CI	6 (30.0%)	8 (40.0%)	14 (35.0%)
95% Exact CI	0.1189, 0.5428	0.1912, 0.6395	0.2063, 0.5168
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.03 (-0.22, 0.29)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.10 (-0.40, 0.20)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.10 (-0.41, 0.23)		
Non-Responder, n(%)			
Last participation date < Day 162 in DB phase	14 (70.0%)	12 (60.0%)	26 (65.0%)
Last participation date \geq Day 162 and TSS at Week 24 not available	5 (25.0%)	5 (25.0%)	10 (25.0%)
Last participation date \geq Day 162 and TSS at Week 24 not available	1 (5.0%)	0	1 (2.5%)
>0% increase from baseline at Week 24	3 (15.0%)	3 (15.0%)	6 (15.0%)
<50% reduction from baseline week 24	8 (40.0%)	7 (35.0%)	15 (37.5%)

95% Exact CI is based on Clopper-Pearson method without stratification.

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TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

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	MMB (N=215)	RUX (N=217)	Total (N=432)
Response Rate of Total Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	20	20	40
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	0	0
Responder, n(%)	7 (35.0%)	7 (35.0%)	14 (35.0%)
95% Exact CI	0.1539, 0.5922	0.1539, 0.5922	0.2063, 0.5168
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.12 (-0.14, 0.37)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	0.00 (-0.30, 0.30)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	0.00 (-0.32, 0.32)		
Non-Responder, n(%)	13 (65.0%)	13 (65.0%)	26 (65.0%)
Last participation date < Day 78 in DB phase	3 (15.0%)	1 (5.0%)	4 (10.0%)
Last participation date >= Day 78 and TSS at Week 12 not available	1 (5.0%)	0	1 (2.5%)
>0% increase from baseline at Week 12	2 (10.0%)	3 (15.0%)	5 (12.5%)
<50% reduction from baseline at week 12	9 (45.0%)	12 (60.0%)	21 (52.5%)

95% Exact CI is based on Clopper-Pearson method without stratification.

TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.

TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

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Intent-to-Treat Analysis Set

	MMB (N=215)	RUX (N=217)	Total (N=432)
Stratum 3			
Transfusion Dependence Yes and Platelet Count > 200X10E9/L	22	21	43
Total Symptom Score Status			
Missing TSS at baseline (excluded from rate calculation)	0	2 (9.5%)	2 (4.7%)
TSS = 0 at baseline	0	0	0
TSS > 0 at baseline	22 (100.0%)	19 (90.5%)	41 (95.3%)
Response Rate of Total Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	22	19	41
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	0	0
Responder, n(%)			
95% Exact CI	4 (18.2%)	9 (47.4%)	13 (31.7%)
95% Exact CI	0.0519, 0.4028	0.2445, 0.7114	0.1808, 0.4809
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	-0.14 (-0.37, 0.09)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.29 (-0.58, -0.01)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.29 (-0.56, 0.02)		
Non-Responder, n(%)			
Last participation date < Day 162 in DB phase	18 (81.8%)	10 (52.6%)	28 (68.3%)
Last participation date < Day 162 in DB phase	4 (18.2%)	0	4 (9.8%)
Last participation date >= Day 162 and TSS at Week 24 not available	0	2 (10.5%)	2 (4.9%)
>0% increase from baseline at Week 24	6 (27.3%)	1 (5.3%)	7 (17.1%)
<50% reduction from baseline week 24	14 (63.6%)	8 (42.1%)	22 (53.7%)

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TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.

TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

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Response Rate of Total Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	22	19	41
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	0	0
Responder, n(%)	5 (22.7%)	6 (31.6%)	11 (26.8%)
95% Exact CI	0.0782, 0.4537	0.1258, 0.5655	0.1422, 0.4294
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.02 (-0.22, 0.25)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.09 (-0.37, 0.19)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.09 (-0.39, 0.21)		
Non-Responder, n(%)	17 (77.3%)	13 (68.4%)	30 (73.2%)
Last participation date < Day 78 in DB phase	3 (13.6%)	0	3 (7.3%)
Last participation date >= Day 78 and TSS at Week 12 not available	0	0	0
>0% increase from baseline at Week 12	6 (27.3%)	2 (10.5%)	8 (19.5%)
<50% reduction from baseline at week 12	14 (63.6%)	13 (68.4%)	27 (65.9%)

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TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.

TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

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	MMB (N=215)	RUX (N=217)	Total (N=432)
Stratum 4			
Transfusion Dependence No and Platelet Count < 100X10E9/L	8	12	20
Total Symptom Score Status			
Missing TSS at baseline (excluded from rate calculation)	0	0	0
TSS = 0 at baseline	0	0	0
TSS > 0 at baseline	8 (100.0%)	12 (100.0%)	20 (100.0%)
Response Rate of Total Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	8	12	20
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	0	0
Responder, n(%)	4 (50.0%)	2 (16.7%)	6 (30.0%)
95% Exact CI	0.1570, 0.8430	0.0209, 0.4841	0.1189, 0.5428
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.39 (-0.01, 0.79)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	0.33 (-0.10, 0.77)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	0.33 (-0.14, 0.71)		
Non-Responder, n(%)	4 (50.0%)	10 (83.3%)	14 (70.0%)
Last participation date < Day 162 in DB phase	1 (12.5%)	1 (8.3%)	2 (10.0%)
Last participation date >= Day 162 and TSS at Week 24 not available	0	0	0
>0% increase from baseline at Week 24	2 (25.0%)	2 (16.7%)	4 (20.0%)
<50% reduction from baseline week 24	3 (37.5%)	9 (75.0%)	12 (60.0%)

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TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

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Response Rate of Total Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	8	12	20
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	0	0
Responder, n(%)	3 (37.5%)	3 (25.0%)	6 (30.0%)
95% Exact CI	0.0852, 0.7551	0.0549, 0.5719	0.1189, 0.5428
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.21 (-0.19, 0.61)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	0.13 (-0.32, 0.57)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	0.13 (-0.33, 0.55)		
Non-Responder, n(%)	5 (62.5%)	9 (75.0%)	14 (70.0%)
Last participation date < Day 78 in DB phase	1 (12.5%)	0	1 (5.0%)
Last participation date >= Day 78 and TSS at Week 12 not available	0	1 (8.3%)	1 (5.0%)
>0% increase from baseline at Week 12	2 (25.0%)	3 (25.0%)	5 (25.0%)
<50% reduction from baseline at week 12	4 (50.0%)	8 (66.7%)	12 (60.0%)

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TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

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	MMB (N=215)	RUX (N=217)	Total (N=432)
Stratum 5			
Transfusion Dependence No and Platelet Count $\geq 100 \times 10^9/L$ and $\leq 200 \times 10^9/L$	45	43	88
Total Symptom Score Status			
Missing TSS at baseline (excluded from rate calculation)	0	0	0
TSS = 0 at baseline	1 (2.2%)	2 (4.7%)	3 (3.4%)
TSS > 0 at baseline	44 (97.8%)	41 (95.3%)	85 (96.6%)
Response Rate of Total Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	44	41	85
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	0	0
Responder, n(%)			
95% Exact CI	14 (31.8%)	17 (41.5%)	31 (36.5%)
95% Exact CI	0.1861, 0.4758	0.2632, 0.5789	0.2629, 0.4762
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.04 (-0.13, 0.21)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.10 (-0.30, 0.11)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.10 (-0.30, 0.12)		
Non-Responder, n(%)			
Last participation date < Day 162 in DB phase	30 (68.2%)	24 (58.5%)	54 (63.5%)
Last participation date \geq Day 162 and TSS at Week 24 not available	4 (9.1%)	2 (4.9%)	6 (7.1%)
Last participation date \geq Day 162 and TSS at Week 24 not available	2 (4.5%)	0	2 (2.4%)
>0% increase from baseline at Week 24	6 (13.6%)	7 (17.1%)	13 (15.3%)
<50% reduction from baseline week 24	24 (54.5%)	22 (53.7%)	46 (54.1%)

95% Exact CI is based on Clopper-Pearson method without stratification.

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TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

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Response Rate of Total Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	45	43	88
TSS = 0 at baseline and TSS >0 or missing at Week 12	1 (2.2%)	2 (4.7%)	3 (3.4%)
Responder, n(%)	13 (28.9%)	11 (25.6%)	24 (27.3%)
95% Exact CI	0.1637, 0.4431	0.1352, 0.4117	0.1832, 0.3781
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.12 (-0.04, 0.28)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	0.03 (-0.16, 0.22)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	0.03 (-0.17, 0.24)		
Non-Responder, n(%)	32 (71.1%)	32 (74.4%)	64 (72.7%)
Last participation date < Day 78 in DB phase	1 (2.2%)	0	1 (1.1%)
Last participation date >= Day 78 and TSS at Week 12 not available	0	1 (2.3%)	1 (1.1%)
>0% increase from baseline at Week 12	11 (24.4%)	10 (23.3%)	21 (23.9%)
<50% reduction from baseline at week 12	30 (66.7%)	29 (67.4%)	59 (67.0%)

95% Exact CI is based on Clopper-Pearson method without stratification.

TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.

TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Source: Listing 16.3.2.1

Data Extracted: CRF data: 01JUL2019

Source: ...\\version5\prog\t-tss24.sas v9.4 Output file: t-tss24.out 09MAR2021:19:52

Table 15.12.2.1: Analysis of Response Rate in TSS at Week 24 and at Week 12
Double-Blind Phase
Intent-to-Treat Analysis Set

	MMB (N=215)	RUX (N=217)	Total (N=432)
Stratum 6			
Transfusion Dependence No and Platelet Count > 200X10E9/L	109	110	219
Total Symptom Score Status			
Missing TSS at baseline (excluded from rate calculation)	1 (0.9%)	1 (0.9%)	2 (0.9%)
TSS = 0 at baseline	1 (0.9%)	1 (0.9%)	2 (0.9%)
TSS > 0 at baseline	107 (98.2%)	108 (98.2%)	215 (98.2%)
Response Rate of Total Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	108	108	216
TSS = 0 at baseline and TSS >0 or missing at Week 24	1 (0.9%)	0	1 (0.5%)
Responder, n(%)			
95% Exact CI	30 (27.8%)	50 (46.3%)	80 (37.0%)
95% Exact CI	0.1959, 0.3722	0.3665, 0.5615	0.3058, 0.4385
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	-0.03 (-0.14, 0.07)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.19 (-0.31, -0.06)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.19 (-0.32, -0.05)		
Non-Responder, n(%)			
Last participation date < Day 162 in DB phase	78 (72.2%)	58 (53.7%)	136 (63.0%)
Last participation date >= Day 162 and TSS at Week 24 not available	16 (14.8%)	1 (0.9%)	17 (7.9%)
Last participation date >= Day 162 and TSS at Week 24 not available	2 (1.9%)	6 (5.6%)	8 (3.7%)
>0% increase from baseline at Week 24	26 (24.1%)	18 (16.7%)	44 (20.4%)
<50% reduction from baseline week 24	59 (54.6%)	51 (47.2%)	110 (50.9%)

95% Exact CI is based on Clopper-Pearson method without stratification.

TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.

TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Source: Listing 16.3.2.1

Data Extracted: CRF data: 01JUL2019

Source: ...\\version5\prog\t-tss24.sas v9.4 Output file: t-tss24.out 09MAR2021:19:52

Table 15.12.2.1: Analysis of Response Rate in TSS at Week 24 and at Week 12
Double-Blind Phase
Intent-to-Treat Analysis Set

	MMB (N=215)	RUX (N=217)	Total (N=432)
Response Rate of Total Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	108	108	216
TSS = 0 at baseline and TSS >0 or missing at Week 12	1 (0.9%)	0	1 (0.5%)
Responder, n(%)	28 (25.9%)	43 (39.8%)	71 (32.9%)
95% Exact CI	0.1797, 0.3525	0.3052, 0.4968	0.2665, 0.3957
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	-0.01 (-0.11, 0.10)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.14 (-0.26, -0.01)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.14 (-0.27, -0.00)		
Non-Responder, n(%)	80 (74.1%)	65 (60.2%)	145 (67.1%)
Last participation date < Day 78 in DB phase	7 (6.5%)	1 (0.9%)	8 (3.7%)
Last participation date >= Day 78 and TSS at Week 12 not available	4 (3.7%)	4 (3.7%)	8 (3.7%)
>0% increase from baseline at Week 12	24 (22.2%)	17 (15.7%)	41 (19.0%)
<50% reduction from baseline at week 12	68 (63.0%)	60 (55.6%)	128 (59.3%)

95% Exact CI is based on Clopper-Pearson method without stratification.

TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.

TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Source: Listing 16.3.2.1

Data Extracted: CRF data: 01JUL2019

Source: ...\\version5\prog\t-tss24.sas v9.4 Output file: t-tss24.out 09MAR2021:19:52

Page 14 of 14