

Table 15.12.1.1: Analysis of Splenic Response Rate 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 Stratum Combined			
Splenic Response Rate at Week 24			
Responder, n(%)	57 ( 26.5%)	64 ( 29.5%)	121 ( 28.0%)
95% Exact CI	0.2074, 0.3294	0.2351, 0.3604	0.2382, 0.3250
Noninferior Proportion Difference - Stratified CMH Method (95% CI)	0.09 (0.02, 0.16)		
p-value	0.014		
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.09 (0.02, 0.16)		
p-value	0.013		
Superior Proportion Difference - Stratified CMH Method (95% CI)	-0.03 (-0.12, 0.05)		
p-value	0.45		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.03 (-0.11, 0.06)		
p-value	0.49		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.03 (-0.12, 0.06)		
p-value	0.52		
Non-Responder, n(%)	158 ( 73.5%)	153 ( 70.5%)	311 ( 72.0%)
Baseline Spleen Volume not available	1 ( 0.5%)	0	1 ( 0.2%)
Spleen Volume at Week 24 not available	31 ( 14.4%)	13 ( 6.0%)	44 ( 10.2%)
>0% spleen volume increase at week 24	26 ( 12.1%)	28 ( 12.9%)	54 ( 12.5%)
<35% spleen volume reduction at week 24	127 ( 59.1%)	140 ( 64.5%)	267 ( 61.8%)
Last participation date < Day 141 in DB phase	24 ( 11.2%)	7 ( 3.2%)	31 ( 7.2%)

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

CMH = Cochran-Mantel-Haenszel

Source: Listing 16.3.1.2

Data Extracted: CRF data: 01JUL2019

Source: ...\\version5\\prog\\t-srr24.sas v9.4 Output file: t-srr24.out 09MAR2021:17:37

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	MMB (N=215)	RUX (N=217)	Total (N=432)
<b>Splenic Response Rate at Week 12</b>			
Responder, n(%)	52 ( 24.2%)	66 ( 30.4%)	118 ( 27.3%)
95% Exact CI	0.1862, 0.3048	0.2437, 0.3700	0.2317, 0.3178
Noninferior Proportion Difference - Stratified CMH Method (95% CI)	0.06 (-0.01, 0.13)		
p-value	0.095		
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.06 (-0.01, 0.13)		
p-value	0.088		
Superior Proportion Difference - Stratified CMH Method (95% CI)	-0.06 (-0.15, 0.02)		
p-value	0.12		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.06 (-0.15, 0.02)		
p-value	0.15		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.06 (-0.16, 0.03)		
p-value	0.16		
Non-Responder, n(%)	163 ( 75.8%)	151 ( 69.6%)	314 ( 72.7%)
Baseline Spleen Volume not available	1 ( 0.5%)	0	1 ( 0.2%)
Spleen Volume at Week 12 not available	20 ( 9.3%)	10 ( 4.6%)	30 ( 6.9%)
>0% spleen volume increase at week 12	15 ( 7.0%)	18 ( 8.3%)	33 ( 7.6%)
<35% spleen volume reduction at week 12	142 ( 66.0%)	141 ( 65.0%)	283 ( 65.5%)
Last participation date < Day 57 in DB phase	14 ( 6.5%)	2 ( 0.9%)	16 ( 3.7%)
<b>Splenic Response Rate at Any Timepoint in DB Phase</b>			
Responder, n(%)	66 ( 30.7%)	83 ( 38.2%)	149 ( 34.5%)
95% Exact CI	0.2460, 0.3733	0.3175, 0.4507	0.3001, 0.3918

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

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
Splenic Response Rate at Week 24			
Responder, n(%)	5 ( 50.0%)	0	5 ( 23.8%)
95% Exact CI	0.1871, 0.8129	0.0000, 0.2849	0.0822, 0.4717
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.50 (0.16, 0.84)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	0.50 (0.15, 0.85)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	0.50 (0.05, 0.81)		
Non-Responder, n(%)	5 ( 50.0%)	11 (100.0%)	16 ( 76.2%)
Baseline Spleen Volume not available	0	0	0
Spleen Volume at Week 24 not available	1 ( 10.0%)	3 ( 27.3%)	4 ( 19.0%)
>0% spleen volume increase at week 24	1 ( 10.0%)	2 ( 18.2%)	3 ( 14.3%)
<35% spleen volume reduction at week 24	4 ( 40.0%)	8 ( 72.7%)	12 ( 57.1%)
Last participation date < Day 141 in DB phase	1 ( 10.0%)	2 ( 18.2%)	3 ( 14.3%)

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

CMH = Cochran-Mantel-Haenszel

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	MMB (N=215)	RUX (N=217)	Total (N=432)
<b>Splenic Response Rate at Week 12</b>			
Responder, n(%)	3 ( 30.0%)	0	3 ( 14.3%)
95% Exact CI	0.0667, 0.6525	0.0000, 0.2849	0.0305, 0.3634
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.30 (-0.01, 0.61)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	0.30 (-0.03, 0.63)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	0.30 (-0.14, 0.65)		
<b>Non-Responder, n(%)</b>			
Baseline Spleen Volume not available	0	0	0
Spleen Volume at Week 12 not available	1 ( 10.0%)	1 ( 9.1%)	2 ( 9.5%)
>0% spleen volume increase at week 12	1 ( 10.0%)	2 ( 18.2%)	3 ( 14.3%)
<35% spleen volume reduction at week 12	6 ( 60.0%)	10 ( 90.9%)	16 ( 76.2%)
Last participation date < Day 57 in DB phase	1 ( 10.0%)	0	1 ( 4.8%)
<b>Splenic Response Rate at Any Timepoint in DB Phase</b>			
Responder, n(%)	5 ( 50.0%)	0	5 ( 23.8%)
95% Exact CI	0.1871, 0.8129	0.0000, 0.2849	0.0822, 0.4717

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

CMH = Cochran-Mantel-Haenszel

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Intent-to-Treat Analysis Set

	MMB (N=215)	RUX (N=217)	Total (N=432)
<b>Stratum 2</b>			
Transfusion Dependence Yes and Platelet Count $\geq 100 \times 10^9/L$ and $\leq 200 \times 10^9/L$	21	20	41
<b>Splenic Response Rate at Week 24</b>			
Responder, n(%)	5 ( 23.8%)	5 ( 25.0%)	10 ( 24.4%)
95% Exact CI	0.0822, 0.4717	0.0866, 0.4910	0.1236, 0.4030
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.09 (-0.14, 0.31)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.01 (-0.29, 0.26)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.01 (-0.30, 0.30)		
Non-Responder, n(%)	16 ( 76.2%)	15 ( 75.0%)	31 ( 75.6%)
Baseline Spleen Volume not available	0	0	0
Spleen Volume at Week 24 not available	5 ( 23.8%)	4 ( 20.0%)	9 ( 22.0%)
>0% spleen volume increase at week 24	3 ( 14.3%)	3 ( 15.0%)	6 ( 14.6%)
<35% spleen volume reduction at week 24	11 ( 52.4%)	11 ( 55.0%)	22 ( 53.7%)
Last participation date < Day 141 in DB phase	4 ( 19.0%)	3 ( 15.0%)	7 ( 17.1%)

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

CMH = Cochran-Mantel-Haenszel

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<hr/>			
Splenic Response Rate at Week 12			
Responder, n(%)	5 ( 23.8%)	0	5 ( 12.2%)
95% Exact CI	0.0822, 0.4717	0.0000, 0.1684	0.0408, 0.2620
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.24 (0.04, 0.43)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	0.24 (0.04, 0.44)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	0.24 (-0.06, 0.52)		
Non-Responder, n(%)	16 ( 76.2%)	20 (100.0%)	36 ( 87.8%)
Baseline Spleen Volume not available	0	0	0
Spleen Volume at Week 12 not available	5 ( 23.8%)	4 ( 20.0%)	9 ( 22.0%)
>0% spleen volume increase at week 12	1 ( 4.8%)	3 ( 15.0%)	4 ( 9.8%)
<35% spleen volume reduction at week 12	11 ( 52.4%)	16 ( 80.0%)	27 ( 65.9%)
Last participation date < Day 57 in DB phase	3 ( 14.3%)	1 ( 5.0%)	4 ( 9.8%)
Splenic Response Rate at Any Timepoint in DB Phase			
Responder, n(%)	6 ( 28.6%)	5 ( 25.0%)	11 ( 26.8%)
95% Exact CI	0.1128, 0.5218	0.0866, 0.4910	0.1422, 0.4294

95% Exact CI is based on Clopper-Pearson method without stratification.  
CMH = Cochran-Mantel-Haenszel  
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Double-Blind Phase  
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
Splenic Response Rate at Week 24			
Responder, n(%)	2 ( 9.1%)	10 ( 47.6%)	12 ( 27.9%)
95% Exact CI	0.0112, 0.2916	0.2571, 0.7022	0.1533, 0.4367
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	-0.19 (-0.38, -0.01)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.39 (-0.64, -0.13)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.39 (-0.62, -0.08)		
Non-Responder, n(%)	20 ( 90.9%)	11 ( 52.4%)	31 ( 72.1%)
Baseline Spleen Volume not available	0	0	0
Spleen Volume at Week 24 not available	4 ( 18.2%)	0	4 ( 9.3%)
>0% spleen volume increase at week 24	4 ( 18.2%)	1 ( 4.8%)	5 ( 11.6%)
<35% spleen volume reduction at week 24	16 ( 72.7%)	11 ( 52.4%)	27 ( 62.8%)
Last participation date < Day 141 in DB phase	3 ( 13.6%)	0	3 ( 7.0%)

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

CMH = Cochran-Mantel-Haenszel

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	MMB (N=215)	RUX (N=217)	Total (N=432)
<b>Splenic Response Rate at Week 12</b>			
Responder, n(%)	3 ( 13.6%)	11 ( 52.4%)	14 ( 32.6%)
95% Exact CI	0.0291, 0.3491	0.2978, 0.7429	0.1908, 0.4854
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	-0.18 (-0.38, 0.02)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.39 (-0.65, -0.12)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.39 (-0.63, -0.08)		
<b>Non-Responder, n(%)</b>			
Baseline Spleen Volume not available	0	0	0
Spleen Volume at Week 12 not available	2 ( 9.1%)	0	2 ( 4.7%)
>0% spleen volume increase at week 12	2 ( 9.1%)	1 ( 4.8%)	3 ( 7.0%)
<35% spleen volume reduction at week 12	17 ( 77.3%)	10 ( 47.6%)	27 ( 62.8%)
Last participation date < Day 57 in DB phase	1 ( 4.5%)	0	1 ( 2.3%)
<b>Splenic Response Rate at Any Timepoint in DB Phase</b>			
Responder, n(%)	3 ( 13.6%)	13 ( 61.9%)	16 ( 37.2%)
95% Exact CI	0.0291, 0.3491	0.3844, 0.8189	0.2298, 0.5327

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

CMH = Cochran-Mantel-Haenszel

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Double-Blind Phase  
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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
Splenic Response Rate at Week 24			
Responder, n(%)	2 ( 25.0%)	0	2 ( 10.0%)
95% Exact CI	0.0319, 0.6509	0.0000, 0.2646	0.0123, 0.3170
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.25 (-0.09, 0.59)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	0.25 (-0.10, 0.60)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	0.25 (-0.22, 0.65)		
Non-Responder, n(%)	6 ( 75.0%)	12 (100.0%)	18 ( 90.0%)
Baseline Spleen Volume not available	0	0	0
Spleen Volume at Week 24 not available	1 ( 12.5%)	1 ( 8.3%)	2 ( 10.0%)
>0% spleen volume increase at week 24	3 ( 37.5%)	4 ( 33.3%)	7 ( 35.0%)
<35% spleen volume reduction at week 24	5 ( 62.5%)	11 ( 91.7%)	16 ( 80.0%)
Last participation date < Day 141 in DB phase	1 ( 12.5%)	0	1 ( 5.0%)

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

CMH = Cochran-Mantel-Haenszel

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	MMB (N=215)	RUX (N=217)	Total (N=432)
<b>Splenic Response Rate at Week 12</b>			
Responder, n(%)	2 ( 25.0%)	0	2 ( 10.0%)
95% Exact CI	0.0319, 0.6509	0.0000, 0.2646	0.0123, 0.3170
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.25 (-0.09, 0.59)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	0.25 (-0.10, 0.60)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	0.25 (-0.22, 0.65)		
<b>Non-Responder, n(%)</b>			
Baseline Spleen Volume not available	0	0	0
Spleen Volume at Week 12 not available	1 ( 12.5%)	0	1 ( 5.0%)
>0% spleen volume increase at week 12	2 ( 25.0%)	3 ( 25.0%)	5 ( 25.0%)
<35% spleen volume reduction at week 12	5 ( 62.5%)	12 (100.0%)	17 ( 85.0%)
Last participation date < Day 57 in DB phase	1 ( 12.5%)	0	1 ( 5.0%)
<b>Splenic Response Rate at Any Timepoint in DB Phase</b>			
Responder, n(%)	2 ( 25.0%)	0	2 ( 10.0%)
95% Exact CI	0.0319, 0.6509	0.0000, 0.2646	0.0123, 0.3170

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

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
Splenic Response Rate at Week 24			
Responder, n(%)	13 ( 28.9%)	6 ( 14.0%)	19 ( 21.6%)
95% Exact CI	0.1637, 0.4431	0.0530, 0.2793	0.1353, 0.3165
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.21 (0.06, 0.35)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	0.15 (-0.02, 0.32)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	0.15 (-0.06, 0.35)		
Non-Responder, n(%)	32 ( 71.1%)	37 ( 86.0%)	69 ( 78.4%)
Baseline Spleen Volume not available	1 ( 2.2%)	0	1 ( 1.1%)
Spleen Volume at Week 24 not available	3 ( 6.7%)	1 ( 2.3%)	4 ( 4.5%)
>0% spleen volume increase at week 24	4 ( 8.9%)	9 ( 20.9%)	13 ( 14.8%)
<35% spleen volume reduction at week 24	29 ( 64.4%)	36 ( 83.7%)	65 ( 73.9%)
Last participation date < Day 141 in DB phase	3 ( 6.7%)	1 ( 2.3%)	4 ( 4.5%)

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

CMH = Cochran-Mantel-Haenszel

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Splenic Response Rate at Week 12			
Responder, n(%)	11 ( 24.4%)	7 ( 16.3%)	18 ( 20.5%)
95% Exact CI	0.1288, 0.3954	0.0681, 0.3070	0.1260, 0.3039
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.15 (0.00, 0.29)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	0.08 (-0.09, 0.25)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	0.08 (-0.13, 0.28)		
Non-Responder, n(%)	34 ( 75.6%)	36 ( 83.7%)	70 ( 79.5%)
Baseline Spleen Volume not available	1 ( 2.2%)	0	1 ( 1.1%)
Spleen Volume at Week 12 not available	1 ( 2.2%)	1 ( 2.3%)	2 ( 2.3%)
>0% spleen volume increase at week 12	2 ( 4.4%)	4 ( 9.3%)	6 ( 6.8%)
<35% spleen volume reduction at week 12	32 ( 71.1%)	35 ( 81.4%)	67 ( 76.1%)
Last participation date < Day 57 in DB phase	1 ( 2.2%)	0	1 ( 1.1%)
Splenic Response Rate at Any Timepoint in DB Phase			
Responder, n(%)	15 ( 33.3%)	8 ( 18.6%)	23 ( 26.1%)
95% Exact CI	0.2000, 0.4895	0.0839, 0.3340	0.1734, 0.3659

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

CMH = Cochran-Mantel-Haenszel

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	MMB (N=215)	RUX (N=217)	Total (N=432)
Stratum 6			
Transfusion Dependence No and Platelet Count > 200X10E9/L	109	110	219
Splenic Response Rate at Week 24			
Responder, n(%)	30 ( 27.5%)	43 ( 39.1%)	73 ( 33.3%)
95% Exact CI	0.1940, 0.3690	0.2993, 0.4886	0.2713, 0.4000
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.04 (-0.06, 0.14)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.12 (-0.24, 0.01)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.12 (-0.25, 0.01)		
Non-Responder, n(%)	79 ( 72.5%)	67 ( 60.9%)	146 ( 66.7%)
Baseline Spleen Volume not available	0	0	0
Spleen Volume at Week 24 not available	17 ( 15.6%)	4 ( 3.6%)	21 ( 9.6%)
>0% spleen volume increase at week 24	11 ( 10.1%)	9 ( 8.2%)	20 ( 9.1%)
<35% spleen volume reduction at week 24	62 ( 56.9%)	63 ( 57.3%)	125 ( 57.1%)
Last participation date < Day 141 in DB phase	12 ( 11.0%)	1 ( 0.9%)	13 ( 5.9%)

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

CMH = Cochran-Mantel-Haenszel

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	MMB (N=215)	RUX (N=217)	Total (N=432)
<b>Splenic Response Rate at Week 12</b>			
Responder, n(%)	28 ( 25.7%)	48 ( 43.6%)	76 ( 34.7%)
95% Exact CI	0.1780, 0.3494	0.3420, 0.5342	0.2842, 0.4141
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	-0.00 (-0.10, 0.09)		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.18 (-0.30, -0.05)		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.18 (-0.31, -0.05)		
<b>Non-Responder, n(%)</b>			
Baseline Spleen Volume not available	0	0	0
Spleen Volume at Week 12 not available	10 ( 9.2%)	4 ( 3.6%)	14 ( 6.4%)
>0% spleen volume increase at week 12	7 ( 6.4%)	5 ( 4.5%)	12 ( 5.5%)
<35% spleen volume reduction at week 12	71 ( 65.1%)	58 ( 52.7%)	129 ( 58.9%)
Last participation date < Day 57 in DB phase	7 ( 6.4%)	1 ( 0.9%)	8 ( 3.7%)
<b>Splenic Response Rate at Any Timepoint in DB Phase</b>			
Responder, n(%)	35 ( 32.1%)	57 ( 51.8%)	92 ( 42.0%)
95% Exact CI	0.2349, 0.4173	0.4209, 0.6145	0.3539, 0.4885

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

CMH = Cochran-Mantel-Haenszel

Source: Listing 16.3.1.2

Data Extracted: CRF data: 01JUL2019

Source: ...\\version5\\prog\\t-srrr24.sas v9.4 Output file: t-srrr24.out 09MAR2021:17:37